

# EXHIBIT A-1

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO THE CASES LISTED BELOW</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

<i>Mullins, et al. v. Ethicon, Inc., et al.</i>	<i>2:12-cv-02952</i>
<i>Sprout, et al. v. Ethicon, Inc., et al.</i>	<i>2:12-cv-07924</i>
<i>Iquinto v. Ethicon, Inc., et al.</i>	<i>2:12-cv-09765</i>
<i>Daniel, et al. v. Ethicon, Inc., et al.</i>	<i>2:13-cv-02565</i>
<i>Dillon, et al. v. Ethicon, Inc., et al.</i>	<i>2:13-cv-02919</i>
<i>Webb, et al. v. Ethicon, Inc., et al.</i>	<i>2:13-cv-04517</i>
<i>Martinez v. Ethicon, Inc., et al.</i>	<i>2:13-cv-04730</i>
<i>McIntyre, et al. v. Ethicon, Inc., et al.</i>	<i>2:13-cv-07283</i>
<i>Oxley v. Ethicon, Inc., et al.</i>	<i>2:13-cv-10150</i>
<i>Atkins, et al. v. Ethicon, Inc., et al.</i>	<i>2:13-cv-11022</i>
<i>Garcia v. Ethicon, Inc., et al.</i>	<i>2:13-cv-14355</i>
<i>Lowe v. Ethicon, Inc., et al.</i>	<i>2:13-cv-14718</i>
<i>Dameron, et al. v. Ethicon, Inc., et al.</i>	<i>2:13-cv-14799</i>
<i>Vanbuskirk, et al. v. Ethicon, Inc., et al.</i>	<i>2:13-cv-16183</i>
<i>Mullens, et al. v. Ethicon, Inc., et al.</i>	<i>2:13-cv-16564</i>
<i>Shears, et al. v. Ethicon, Inc., et al.</i>	<i>2:13-cv-17012</i>
<i>Javins, et al. v. Ethicon, Inc., et al.</i>	<i>2:13-cv-18479</i>
<i>Barr, et al. v. Ethicon, Inc., et al.</i>	<i>2:13-cv-22606</i>
<i>Lambert v. Ethicon, Inc., et al.</i>	<i>2:13-cv-24393</i>
<i>Cook v. Ethicon, Inc., et al.</i>	<i>2:13-cv-29260</i>
<i>Stevens v. Ethicon, Inc., et al.</i>	<i>2:13-cv-29918</i>
<i>Harmon v. Ethicon, Inc., et al.</i>	<i>2:13-cv-31818</i>
<i>Snodgrass v. Ethicon, Inc., et al.</i>	<i>2:13-cv-31881</i>
<i>Miller v. Ethicon, Inc., et al.</i>	<i>2:13-cv-32627</i>
<i>Matney, et al. v. Ethicon, Inc., et al.</i>	<i>2:14-cv-09195</i>
<i>Jones, et al. v. Ethicon, Inc., et al.</i>	<i>2:14-cv-09517</i>
<i>Humbert v. Ethicon, Inc., et al.</i>	<i>2:14-cv-10640</i>
<i>Gillum, et al. v. Ethicon, Inc., et al.</i>	<i>2:14-cv-12756</i>
<i>Whisner, et al. v. Ethicon, Inc., et al.</i>	<i>2:14-cv-13023</i>
<i>Tomblin v. Ethicon, Inc., et al.</i>	<i>2:14-cv-14664</i>
<i>Schepleng v. Ethicon, Inc., et al.</i>	<i>2:14-cv-16061</i>
<i>Tyler, et al. v. Ethicon, Inc., et al.</i>	<i>2:14-cv-19110</i>
<i>Kelly, et al. v. Ethicon, Inc., et al.</i>	<i>2:14-cv-22079</i>
<i>Lundell v. Ethicon, Inc., et al.</i>	<i>2:14-cv-24911</i>

*Cheshire, et al. v. Ethicon, Inc., et al.*

2:14-cv-24999

*Burgoyne, et al. v. Ethicon, Inc., et al.*

2:14-cv-28620

*Bennett, et al. v. Ethicon, Inc., et al.*

2:14-cv-29624

**Rule 26 Report of Kimberly Kenton, MD, MS**  
**Board-certified, Female Pelvic Medicine & Reconstructive Surgery**

This is my report related to the design of Ethicon's TVT™ retropubic sling. My opinions relate to TVT™ being safe for its intended use in treating stress urinary incontinence and describing how the benefits of TVT™ significantly outweigh the risks associated with the procedure. All of my opinions are held to a reasonable degree of medical certainty, and I reserve the right to amend my report and opinions based on new information. I have reviewed the expert reports of plaintiffs' experts and have included my reliance materials as an attached exhibit.

**I. Background and Education:**

I am board-certified by the American Boards of Obstetrics & Gynecology and Urology in Female Pelvic Medicine & Reconstructive Surgery and by the American Board of Obstetrics & Gynecology in Obstetrics & Gynecology. My current position is Professor of Obstetrics/Gynecology and Urology, Division Chief of Female Pelvic Medicine & Reconstructive Surgery (FPMRS) at Northwestern University, Feinberg School of Medicine in Chicago, Illinois. I am an internationally recognized leader in Female Pelvic Medicine & Reconstructive Surgery/Urogynecology for my expertise in the clinical and surgical care of women with urinary incontinence and pelvic organ prolapse as well as high-quality surgical outcomes and comparative effectiveness research. I earned a Master of Science in Clinical Research Design and Statistical Analysis at the University of Michigan, Ann Arbor and served as the principal investigator on multiple NIH (National Institute of Health) grants studying urinary incontinence.

I was part of a multicenter group who designed, implemented and published the largest US comparative effectiveness trial comparing transobturator midurethral sling to the gold standard retropubic midurethral sling. This landmark study showed the efficacy and safety of both types of synthetic midurethral sling. Gynecare TVT™ was *intentionally* selected as the retropubic sling to be used in this study due to previously published large trials demonstrating efficacy and safety of the procedure and the mesh. I have over 170 peer-reviewed scientific research publications, many of which pertain to the etiology and treatment of urinary incontinence. Recently, the American College of Obstetricians & Gynecologist and the American Urogynecologic Society asked that I co-author a national Practice Bulletin summarizing current evidence for the evaluation and treatment of urinary incontinence in women. I also authored the bladder neck fascial sling section of UpToDate. UpToDate is the only clinical knowledge resource for

physicians with research studies demonstrating improved outcomes. A subject matter expert and at least two different physician reviewers perform a comprehensive review of the literature and develop clear evidenced-based recommendations for treatment. Both documents support published randomized trial and meta-analysis data endorsing midurethral sling as first line treatment for stress incontinence in women based on safety and efficacy.

## **II. Experience:**

My experience as a surgeon, educator, and researcher resulted in my leadership in our national certifying and credentialing organizations. The American Boards of Obstetrics & Gynecology and Urology selected me to serve on the joint Female Pelvic Medicine & Reconstructive Surgery Division charged with developing the exam to certify individual surgeons in FPMRS. I worked with a small group of six urogynecologists and urologists from across the US to write the exam used to credential sub-specialty surgeons performing surgery for urinary incontinence in women. Likewise, I was part of the team who worked with Accreditation Counsel of Graduate Medical Education (ACGME) to develop guidelines for fellowship training in FPMRS.

## **III. Board Certification:**

Board certification is a voluntary process and differs from medical licensure in that medical licensure sets minimum competency requirements to diagnose and treat patients; it is not specialty specific. Board certification demonstrates a physician's exceptional expertise in a particular specialty. In addition, the American Board of Medical Specialties [ABMS (parent board to ABOG and ABU)] requires that all certified physicians engage in on-going maintenance of certification to ensure they stay current of advances in the evaluation and treatment of patients by that specialty. Patients, physicians, health care providers, insurers and quality organizations look for these markers as the best measure of a physician's knowledge, experience, and skills to provide quality health care within a given specialty, recognizing the growing need for research and high-quality specialty care for women with urinary incontinence and pelvic floor disorders beyond that provided by urologists and gynecologists. The ABMS officially approved the specialty of **Female Pelvic Medicine and Reconstructive Surgery** in the spring of 2011. In so doing, ABMS acknowledged that care for women with complex pelvic floor disorders (such as urinary and fecal incontinence, and pelvic organ prolapse) requires subspecialty training and certification beyond the training acquired by a general obstetrician-gynecologist or a general urologist. In June of 2013, the American Board of Obstetrics and Gynecology and the American Board of Urology certified the first individual physicians. My CV is attached as Exhibit "A".

I am charging \$600 per hour for meetings and to review documents, \$700 per hour for deposition testimony, and \$4,000 per day for trial testimony. I have not testified as an expert in the last four years.

#### IV. Professional Societies:

I am also a member and have held leadership positions in all of our major professional organizations, including:

- American Urogynecologic Society where I served on, then chaired the Education Committee; the Board of Directors; Grant Review Committee; and Leadership Committee.
- Society of Gynecologic Surgeons where I served on the Research Committee; served then chaired the Education Committee; and the Executive Committee.
- American College of Obstetricians & Gynecologist where I served on the Practice Bulletins Committee for Gynecology and the Clinical Document Review Panel. Most recently, I chaired the committee responsible for the first Prolog in Female Pelvic Medicine & Reconstructive Surgery.
- Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction where I participated on a small work group who developed a urodynamics curriculum for urology residents.
- American Urologic Association.
- International Urogynecologic Society where I served on the Research & Development Committee.
- International Continence Society.

I devote my time and energy to these organizations as well as our certifying/credentialing boards (ABOG, ABU, and ACGME) because these organizations are dedicated to improving health outcomes for women with urinary incontinence and other pelvic floor disorders. Nearly all of the organizations dedicate significant resources to developing evidenced-based guidelines to help clinicians and patients chose the best health care treatments, which optimize outcomes and complications. In fact, most of the organizations (AUGS, SUFU, IUGA, and AUA) developed thoughtful, evidenced-based statements supporting the use of synthetic midurethral slings as a primary treatment for stress urinary incontinence in women. The mission of American Urogynecologic Society, the leader in FPMRS, is to “promote the highest quality patient care through excellence in education, research and advocacy.” The Society developed an evidenced based statement on role of midurethral slings and accompanying FAQs for providers and patients because of their commitment to our patients.

Learning how to perform surgery using the retropubic midurethral sling is listed as a learning objective in the AUA National Medical Student Curriculum dated August of 2012. Additionally, the AUGS Resident Learning Objectives suggest residents should

“understand the differences between traditional and minimally invasive surgical approaches, e.g., open Burch versus laparoscopic Burch, and traditional pubovaginal sling versus mid-urethral sling.” The resident should also be able to “discuss risks, benefits, and expected outcomes of nonsurgical and surgical management of SUI.” Moreover, the residents should “understand and perform a mid-urethral sling, using either retropubic or transobturator approach.” Residents are also expected to be familiar with synthetic foreign body materials, as they should “understand the vital characteristics of synthetic grafts, e.g., pore size, mono versus polyfilament, material types; understand the relative indications for, and complications associated with, each category of grafts; and understand the management of graft complications, both surgical and non-surgical.” The ACGME Competencies require fellows to demonstrate competence in performing surgery for urinary incontinence using synthetic slings. The ABOG and ABU Guide to Learning Female Pelvic Medicine and Reconstructive Surgery suggests that FPMRS fellows should be able to perform and describe the complications associated with synthetic retropubic slings and be able to manage complications associated with continence surgery, including: cystotomy, fistula, persistent or recurrent urinary incontinence symptoms, voiding dysfunction or retention, foreign body associated complications, and urinary tract infection. It is important to note that FPMRS fellows are also expected to cite published success and complication rates for each continence procedure, quality of studies, and level of evidence. Lastly, the IUGA Guidelines for training in FPMRS suggest that trainees should receive experience in the theory, practice, and performance of minimally invasive slings, mesh use in repairs, use of various graft materials, and sling procedures – retropubic, pubo-vaginal, mid-urethral and transobturator. As such, residents and fellows are expected to become familiar and keep current with the frequency and severity of complications associated with midurethral slings through their education, training, experience, and review of the medical literature.

I chose to use Ethicon TVT™, TVT™ Exact, and TVT-O™ for the primary surgical treatment of stress urinary incontinence in my patients who selected midurethral sling for over a decade because of the magnitude of the clinical data demonstrating their safety and efficacy. I have never received any financial support from Ethicon.

#### **V. Procedures Performed:**

I have regularly performed surgery to treat stress urinary incontinence since starting my ABOG/ABU accredited fellowship in 1999. First line surgical treatments of stress incontinence at that time were Burch colposuspension and bladder neck fascial sling. I performed countless numbers of both procedures, which involve an abdominal incision and are significantly more invasive than midurethral slings. From 2002-2004, I was part of a large federally supported comparative effectiveness trial comparing outcomes of Burch and bladder neck fascial slings, SISTEr (Stress Incontinence Surgical Treatment Efficacy Trial) directly comparing Burch and bladder neck fascial slings (Albo

M. NEJM 2007). Unlike a case series evaluating autologous fascial slings, which is considered level 4 evidence, the SISTER study provides level 1 evidence.

In 2000, the National Institutes of Diabetes, Digestive and Kidney Diseases (NIDDK) established the Urinary Incontinence Treatment Network (UITN), recognizing the need for well-designed outcomes studies for urinary incontinence treatment in women as previous studies had methodological flaws and/or limitations that precluded definitive conclusions about the relative efficacy or differences in complications between procedures. These limitations included variability in case definition, failure to account for known confounders, lack of standardization of technique, short duration of follow-up, poor generalizability, inadequate power to detect clinically important differences, lack of assessment of complications, and marked variability in outcome assessment (UITN. Urology 2005). Randomized controlled trials or comparative effectiveness trials are considered the best of all research designs because the act of randomizing patients to receive one intervention or the other ensures that, on average, all other factors are equal between the groups. Therefore, any significant differences in outcomes or complications between the groups can be attributed to the intervention or procedure and not to some other factor. Burch and bladder neck slings were selected for comparison by the UITN since they were considered the 'gold standard' procedures for treating stress incontinence in the US at that time; although expert opinion existed regarding the efficacy of the procedures, no prospective comparative data was available to support or refute "expert opinions". We now have 2-year and 5-year outcome and complication data directly comparing these two procedures (Albo M. NEJM 2007, Brubaker L. JAMA 2012).

I expanded my surgical counseling to include midurethral sling (Ethicon TVT™ in particular) in the mid-2000s based on evolving scientific data, in particular a 14-center randomized trial done in the UK comparing Ethicon TVT™ to Burch colposuspension (Ward KL. BMJ 2002, Ward KL. AJOG 2004, Ward KL. BJOG 2007). Midurethral slings are less invasive, have fewer complication, (less prolonged voiding dysfunction, and result in quicker recovery times for patients. As part of a clinical research network supported by the National Institutes of Health, I helped design, implement and publish the largest US comparative effectiveness trial comparing transobturator midurethral sling to the gold standard retropubic midurethral sling. This landmark study showed the efficacy and safety of both types of synthetic midurethral slings at 1, 2 and 5-years after surgery (Richter HE. NEJM 2010, Albo M. J Urol. 2012, Kenton K. J Urol 2015). Gynecare TVT™ was *intentionally* selected as the retropubic sling to be used in this study due to previously published large trials demonstrating efficacy and safety of the procedure and the mesh. At the start of the study period (similar to the UK study comparing TVT™ to Burch), only mechanically cut mesh was available, so these data reflect clinical outcomes of mechanically cut mesh.

I have performed over a 1,000 TVT™ and TVT™ Exact procedures and currently offer retropubic midurethral slings as a first line procedure in women with stress urinary

incontinence. As a result, I have significant clinical experience with both mechanically and laser cut sling mesh. Similar to the large body of published clinical outcomes data – including over 100 RCTs, long-term studies<sup>1</sup>, Cochrane Reviews<sup>2</sup>, Registries<sup>3</sup>, Meta-Analyses and Systematic Reviews<sup>4</sup> – I have not found any clinically relevant differences in the design properties or outcomes suggesting clinically significant differences between mechanically cut and laser cut TVT. While theoretical and laboratory data may offer interesting hypotheses worthy of clinical studies, there are presently no substantial comparative clinical data in women with stress incontinence suggesting benefit of one over the other. Given the low rates of mesh exposures in well-designed published trials and long-term studies with follow-up ranging from 10-17 years using mechanically cut sling mesh, it is unlikely that comparative studies of mechanically and laser cut meshes will ever be feasible due to impractically large sample sizes that would be required to show a marginal difference, if any, between mechanically cut and laser cut TVT.

I continue to counsel each woman planning surgery for stress urinary incontinence about the full range of surgical alternatives, including Burch colposuspension, bladder neck fascial sling, and both retropubic and transobturator midurethral slings, but recommend Amid Type I polypropylene, macroporous synthetic midurethral slings, such as TVT, for the majority of my patients. Each procedure is associated with reasonable success rates, but differ with respect to complications and recovery time, and individual women should be allowed to select the risk profile that most suits her goals. The majority of women select the retropubic midurethral sling. However, in select women who decline or are not candidates for synthetic mesh slings, bladder neck fascial slings remain an important, effective treatment option. Several conditions in which autologous fascia sling should be considered include:

- Women with severe stress incontinence and a non-mobile, fixed urethra, bladder neck sling may be preferable due to its slightly more obstructive nature. Some surgeons will place a bladder neck fascial sling under more tension (more obstructive) than a synthetic sling secondary to risks of urethral erosion.
- Women undergoing urethral reconstruction (eg: diverticulectomy or fistula repair) should be considered for concomitant bladder neck slings. Several investigators reported good incontinence outcomes and low complication rates after urethral diverticulectomy and autologous fascial sling.

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<sup>1</sup> Nilsson (2004, 2008, 2013), Liapis (2008), Kuuva (2005), Celebi (2009), Prien-Larsen (2009), Song (2009), Lee (2010), Reich (2011), Shao (2011), Li (2012), Ward (2007), Kenton (2015), Cresswell (2008), Valpas (2014), Laurikainen (2014), Constantini (2015), Olsson (2010), Groutz (2011), Aigmueller (2011), Heinonen (2012), Serati (2012), Svenningsen (2013).

<sup>2</sup> Ford (2015), Ogah (2009, 2011), Novara (2007, 2008, 2010), Latthe (2007, 2010), Rehman (2011), Lapitan (2012).

<sup>3</sup> Kuuva (2002), Schraffordt (2006, 2007), Tamussino (2001), Nilsson (2012), Svenningsen (2013), Dyrkorn (2010), Tincello (2011).

<sup>4</sup> Schimpf (2014), Tommaselli (2015), Cox (2013)



- Women who had complications from prior mesh placed in the anterior vagina (for incontinence or prolapse) may be candidates for autologous fascia sling. Several case series report good outcomes with removal of prior mesh and/or placement of autologous fascia sling (Milose JC. J Urol. 2015); however, multiple studies also report good outcomes when a second synthetic midurethral sling is placed (Pardon AM. Obstet Gynecol. 2013).

Although the aforementioned patients may benefit from a bladder neck fascial sling, the majority of patients seeking surgical treatment for uncomplicated stress incontinence are best suited for a synthetic midurethral sling. The bladder neck fascial sling has its place in a surgeon's armamentarium, but should not be considered the gold standard procedure secondary to increased complications and recovery. Historically, bladder neck fascial slings were reserved for women with 'intrinsic sphincter deficiency' or severe stress incontinence, while Burch was the first line treatment. The limitation of this treatment strategy was related to diagnosis of intrinsic sphincter deficiency. Numerous clinical investigators tried over the years to determine which patients should get bladder neck slings and which Burch colposuspension using various measure of urethral function (Valsalva Leak Point Pressures, Maximum Urethral Closure Pressures, Electromyography) to diagnose intrinsic sphincter deficiency. Unfortunately, NONE of the measures discriminated surgical success/failures, thus limiting their clinical utility. To date the BEST comparative data available is the UITN's SISTEr study, published in the New England Journal of Medicine,. Within the last 10 years, the synthetic midurethral sling has replaced traditional, more invasive abdominal procedures as the gold standard for the primary surgical treatment of stress incontinence.

## **VI. Overview of Stress Urinary Incontinence:**

Urinary incontinence affects 10–70% of women living in a community setting and up to 50% of nursing home residents and is often the main reason for nursing home admission. Prevalence of incontinence increases gradually during reproductive years peaking around middle age, and then steadily increasing with aging (DuMoulin MF. Scandinavian J Caring Sci. 2009, Offermans MP. Neurourol Urodynam. 2009). Despite the prevalence of urinary incontinence, many women are hesitant to seek care or discuss their symptoms with a health care provider. In a survey of women in the United States, only 45 percent of women who reported at least weekly urine leakage sought care for their incontinence symptoms (Hannestad YS. J Clinical Epi 2000). As a result, many incontinent women live with physical, functional, and psychological limitations and diminished quality of life at home and at work.

In 1995, the estimated annual direct cost of urinary incontinence in the United States was \$12.43 billion (Wilson L. Obstet Gynecol. 2001), which was greater than the annual direct costs for breast, ovarian, cervical, and uterine cancers combined (Varmus H. Disease-Specific Estimates of Direct and Indirect Costs of Illness and NIH Support. Bethesda (MD): Department of Health and Human Services, National Institutes). In

2001, the demand for treatment for pelvic floor disorders was estimated to increase by 45% over the next 30-years with a commensurate rise in health care costs (Luber KM. AJOG. 2001). In the United States in 2010, approximately 260,000 women underwent surgical treatment of stress urinary incontinence (Urogyn surgical mesh update, FDA July 2011). Stress urinary incontinence affects 16% of adult women with 78% reporting their symptoms to be bothersome and with nearly 30% reporting their symptoms to be moderately to extremely bothersome. In 2010, approximately 260,000 women in the United States underwent surgical treatment of SUI.<sup>5</sup>

Since their introduction in the 1990s, midurethral slings have become the primary surgical treatment for stress urinary incontinence in women with a 27% increase in the rate of surgical management of stress urinary incontinence from 2000 to 2009, the majority of which was secondary to increase in number of sling procedures (Anger JT Urol 2009, Jonsson Funk M Obstet Gynecol 2012). Additionally, published surveys and literature have shown a significant increase in synthetic midurethral slings, which corresponds with a sharp decline in the usage of autologous fascial sling and Burch procedures over the past ten years. A 2015 Cochrane Review of the peer-reviewed literature concluded that “midurethral sling operations are the most extensively researched surgical treatment for stress incontinence in women, have a good safety profile.... and are highly effective in the short and medium term... accruing evidence demonstrates their effectiveness in the long term.” (Ford AA. Cochrane Database Syst Rev. 2015). The authors also conclude that midurethral slings have a “positive impact on improving quality of life of women with stress incontinence.”

Another meta-analysis of 62 randomized trials concluded that midurethral slings are as effective as Burch colposuspension and bladder neck fascial slings, but are associated with shorter operative times, quicker recovery, and fewer postoperative complications.<sup>6</sup> Short-term cure rates of midurethral slings were comparable to bladder neck sling (73% vs 71%, RR 1.0 95% CI 0.9-1.1), open Burch colposuspension (79% vs 82%, RR 1.0, 95% CI 0.9-1.0), and laparoscopic colposuspension (82% vs 74%, RR 1.1, 95% CI 1.0-1.2). Rates of new onset urgency and urgency incontinence are **lower** after midurethral sling compared to bladder neck slings.

Several large multicenter trials compared retropubic and transobturator midurethral slings (Richter HE. NEJM. 2012). The Trial of Midurethral Slings (TOMUS) randomized women with stress predominant urinary incontinence to TVT™ (mechanically cut mesh) or transobturator midurethral slings. Using a composite primary outcome (negative cough stress test, negative pad test, no retreatment, no self-reported symptoms, and no leakage episodes on voiding diary) the procedures were equivalent (81% for TVT™ and 78% for transobturator) at one-year. However, at 24

<sup>5</sup> ACOG and AUGS: Committee Opinion Number 603 – Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment.

<sup>6</sup> Ogah 2011 Cochrane Review.

months, neither objective or subjective success rates met the predefined criteria for equivalence. Voiding dysfunction was more common with retropubic slings (2.7% vs 0%), but neurologic symptoms were more common with transobturator slings (9.4% vs 4.0%). The most common adverse effect was UTI (26%). ***Mesh complications (3.4%) were uncommon (16 exposures and 2 erosions) in the first 2-years.*** There were only 7 new mesh erosions (3 TVT™, and 4 transobturator slings) between year 2 and 5.

While urethral bulking agents are rarely used as a primary treatment for stress urinary incontinence, they remain an option for women with persistent stress urinary incontinence or women with commodities who cannot tolerate anesthesia or surgery. A recent Cochrane Review found that urethral bulking agents are less effective than sling surgery with 1.7- to 4.7-fold increased likelihood of cure with surgical treatment.

## **VII. Alternative Treatments for Stress Incontinence:**

### ***A. Pelvic Floor Muscle Exercises***

Pelvic floor muscle exercises are effective treatment for stress incontinence. Approximately half of women with stress predominant urinary incontinence are satisfied one year after starting pelvic floor muscle training. A recent trial compared pelvic floor muscle training to midurethral sling for treatment of stress urinary incontinence. Forty-nine percent of women in the pelvic floor muscle-training group crossed over to surgery and 11% of women in the surgery group crossed over to physical therapy. In intent to treat analysis, subjective cure rates were 85% in the surgery group and 53% in the physical therapy group suggesting initial midurethral sling surgery results in higher cure rates than physical therapy at one-year.

### ***B. Incontinence Pessaries***

Incontinence pessaries can improve stress urinary incontinence symptoms in some women by increasing urethral resistance. One randomized trial demonstrated similar satisfaction with stress incontinence symptoms one-year after pessary and behavioral-physical therapy (Richter HE. Obstet Gynecol 2010). There was no benefit to combined therapy with pessary and behavioral-physical therapy. Health care providers should discuss both pessary and behavioral-physical therapy as effective conservative therapies for stress urinary incontinence. Patients will likely select based on personal factors; pessary offers more immediate symptom control, while physical therapy may offer long-term neuromuscular changes.

### ***C. Behavioral Modification***

Level I evidence exists supporting role of some behavioral modifications in the treatment of urinary incontinence. In one study, behavioral therapy including group and individual instruction, scheduled voiding, diary keeping, and pelvic floor muscle exercises resulted in a 50% reduction in mean incontinence episodes compared with a 15% reduction in controls. Behavioral training with biofeedback did not reduce incontinence episodes more than providing verbal feedback or receiving a self-help

booklet. Therefore, behavioral therapy improves symptoms of urinary incontinence and can be recommended as a noninvasive treatment in many women.

Obesity is an independent risk factor for the development of incontinence, with obese women having a 4.2-fold greater risk of stress urinary incontinence than those with a normal body mass index. Several trials demonstrate that moderate weight loss can improve stress urinary incontinence symptoms in overweight and obese women suggesting that even moderate weight loss can improve stress urinary incontinence symptoms.

#### ***D. Urethral Bulking Agents***

While urethral bulking agents are rarely used as a primary treatment for stress urinary incontinence, they remain an option for women with persistent stress urinary incontinence or women with comorbidities who cannot tolerate anesthesia or surgery. A recent Cochrane Review found that urethral bulking agents are less effective than sling surgery with 1.7- to 4.7-fold increased likelihood of cure with surgical treatment.

#### ***E. When to Recommend Surgical Treatment***

Surgery is indicated for appropriately counseled women with stress urinary incontinence who decline or have insufficient symptom control after conservative treatment. While surgical treatments are associated with higher success rates than conservative therapy, surgery is also associated with increased morbidity, postoperative voiding difficulty and development urgency incontinence. Recent randomized trial data demonstrate a higher subjective improvement (91% vs 64%) and objective cure rates (77% vs 59%) one-year after midurethral sling compared to physical therapy, suggesting midurethral sling is an appropriate first-line treatment in appropriately counseled women. Each woman must balance her symptom bother, quality of life impact, and goals for treatment when deciding upon surgical management of her stress urinary incontinence. The projected total number of women who will undergo SUI surgery will increase 47.2% from 210,700 in 2010 to 310,050 in 2050.<sup>7</sup>

#### ***F. Laser cut vs. mechanically cut mesh***

I regularly review the medical literature related to surgical procedures and devices used to treat stress urinary incontinence, and I have never seen any clinical outcome literature that would suggest mechanically cut mesh is inferior or causes complications; nor have I seen any literature suggesting that laser cut is superior and causes fewer complications. In a study from 2006 comparing a laser cut mesh to mechanically cut TVT™-O, which is made from the same material as mechanically cut TVT™, the authors found statistically more vaginal mesh exposures (7.29% vs. 1.78%) in the Obtape laser cut group than in the mechanically cut TVT™-O group at 36 months follow-up and no cases of urethral erosions. This nearly 2% mesh exposure rate of the

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<sup>7</sup> Wu (2011): Predicting the number of women who will undergo incontinence and prolapse surgery, 2010 to 2050.

mechanically cut mesh is similar to exposure rates of mechanically cut mesh in large multicenter trials and meta-analyses. In addition, the weight of Obtape as 90 g/m<sup>2</sup> and TVT™-O as 94 g/m<sup>2</sup>, suggests that weight of the mesh was not a contributing factor to an increase in mesh exposures.

The edges of mechanically cut TVT™ mesh are not sharp and do not cut into tissue and cause complications. The unsealed edges provide for greater tissue integration through the 'Velcro effect'. In a 2011 randomized trial by Neuman and colleagues evaluating TVT™-O (mechanically cut) and TVT™-Secur (laser cut), the authors hypothesized that higher rates of dyspareunia in the TVT™-Secur group may be explained "in part by the rigidity and reduced flexibility of the synthetic polypropylene implant because it is laser cut, which tends to result in a stiff tape edge. As a result, the overlying vaginal mucosa is constantly traumatized, much more than it would be with use of mechanically cut tape."

Additionally, I am aware of a study<sup>8</sup> comparing Advantage, which has a laser cut section, to mechanically cut TVT, in which the authors suggested that the heat-treated section of the Advantage sling made the tape stiffer and less elastic in animal and in vitro studies. They theorized that the increase in overactive bladder and voiding difficulty issues with the Advantage "could be related to the slightly stiffer nature of the Advantage sling." Moreover, the authors noted that TVT "is commonly acknowledged as the gold standard of MUS by virtue of its extensive safety and efficacy data in the literature." Regardless, 93.2% of TVT patients and 92.6% of Advantage patients would recommend the procedure to a friend. In a different study<sup>9</sup> comparing Lynx to TVT, the authors found an increased rate of vaginal mesh exposures with Lynx (4% with Lynx vs. 0% with TVT) and wondered if "the heat sealed edges in the Lynx system increased its resistance to deformation, thus increasing the risk of erosion." They suggested that "the open weave Prolene [TVT] mesh also has unique biomechanical properties with low stiffness and low resistance to deformation, which may be the reason for its low risk of erosion." Again, patient satisfaction rates were similar at 92% for both products.

Furthermore, I am also aware of an internal email from an engineer at Ethicon who suggested that laser cut mesh would cause mesh to lay flat and reduce roping and curling, which would then reduce retention rates. Unfortunately, this theory is not substantiated in the peer-reviewed literature, nor have I noticed a difference in retention rates in my patient after placement of mechanically cut or laser cut TVT™ mesh. Likewise, I have also seen a company document suggesting that laser cut TVT™ mesh is 3 times stiffer than mechanically cut mesh when it was subjected to benchtop testing under strain, and the suggestion that stiffer mesh causes an increase in complications, such as pain and mesh exposure. Again, this is an unsubstantiated theory that would suggest a design change is warranted based on clinical data, or that

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<sup>8</sup> Lim (2010): Do the Advantage slings work as well as the tension-free vaginal tapes? Int Urogyn J (2010).

<sup>9</sup> Aarwalla (2008)

laser cut results in statistically significant lower adverse events. I have not seen a difference in complication rates in the literature or my patients.

**VIII. TVT is Reasonably Safe for its Intended Use in Treating SUI: Supported by Cochrane Reviews, Meta-Analyses, Systematic Reviews, RCTs, Prospective and Retrospective Clinical Cohort Studies, Practice Patterns and Surveys, Society Position Statements and Guidelines, Review Articles, Medical Textbooks, My Clinical Experience, Education, My Review of the Medical Literature, and My Discussions with Thought Leaders:**

1. Midurethral slings are the most extensively researched surgical treatment for stress incontinence in women. They have a good safety profile and are highly effective in the short and medium term with accruing evidence demonstrating their effectiveness in the long term.
2. The midurethral sling has replaced alternative procedures (Burch colposuspension and bladder neck fascial sling) as the gold standard, first-line, surgical option for treating stress urinary incontinence. The peer reviewed medical literature and major medical professional societies support the position that polypropylene midurethral slings are the preferred surgical treatment option for stress urinary incontinence over Burch colposuspension and bladder neck fascial slings in most women based on efficacy and safety data.
3. Although controversy exists over the role of synthetic mesh using in vaginal repair of prolapse, there are substantial safety and efficacy data that support the role of synthetic mesh midurethral sling as a primary treatment option for stress incontinence in women. For this reason, and to clarify the uncertainty for patients and health care providers, the American Urogynecologic Society and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction published a position statement recognizing polypropylene mesh slings as the 'standard of care' in the surgical treatment of stress incontinence.
4. Midurethral sling surgery results in higher subjective and objective cure rates than pelvic floor physical therapy and pessary use in women with stress urinary incontinence.
5. Ethicon's TVT™ has a good safety and efficacy profile for treatment of stress incontinence in women, as evidenced in multiple randomized comparative effectiveness trials.
6. The benefits and utility of midurethral sling, including TVT™ significantly outweigh the potential risk of harms in most women who desire surgical treatment of stress incontinence.

7. TVT™ has been safely for over 17 years. TVT™ is safe and effective in a variety of patients with similar results from a wide range of surgeons and patients. A significant number of RCTs, long-term studies, and Cochrane Reviews have shown that retropubic midurethral sling is reasonably safe for its intended use. Since its introduction as a minimally invasive procedure, the TVT has grown rapidly in popularity as a first line treatment of stress urinary incontinence. The TVT has also shown excellent results in patients with previous failed incontinence surgery, intrinsic sphincter deficiency, and mixed incontinence. The reasons behind this success story include the relative ease of performing under local or regional anesthesia, outpatient procedure, good success and satisfaction rates, low complication rates, decreased postoperative pain, and fast recovery.
8. The medical literature does not support the theory that a change in the design of TVT™ would reduce or eliminate the already low mesh complications (2-3%) associated with TVT™ mesh, while also maintaining high cure rates.
9. The properties and characteristics of the TVT™ mesh are appropriate and desired for the intended use of treating stress urinary incontinence. The TVT™ mesh is classified as an Amid Type I, macroporous, polypropylene, monofilament mesh, and its safety profile is supported by numerous medium to long-term clinical studies. The vast body of clinical literature evaluating TVT™ has shown that the design of TVT™ is appropriate and desired as a result of the excellent outcomes regarding safety, patient satisfaction, and efficacy. Studies have shown that the Prolene mesh used in TVT has lower complications than the Amid Type III meshes that were previously used, such as Gore-Tex, Mersilene, and Teflon.
10. Current clinical outcome data in women with stress incontinence suggest that mechanically cut mesh is safe and effective as the majority of randomized trial data and long-term studies include mechanically cut TVT™ mesh. The way the mesh is cut does not seem to have a clinically significant impact on the mesh in actual women having surgery for stress incontinence. The TVT™ mesh is such that the 1.1cm width of tape allows for sufficient construction of pores that are able to provide the necessary tissue integration and support under the midurethra. The TVT™ mesh is appropriate for handling and lays flat under the midurethra. The theory that a 1.1cm strip of a lighter weight, larger pore mesh would provide the same lasting support without roping or curling is not supported in the clinical literature. The TVT pore size allows for the intended tissue ingrowth which prevents pore collapse and does not foster shrinkage or contraction (Nilsson 2013, Lo 2004, Lukacz 2003, Rinne 2011).
11. Based on outcome literature, the pore size and weight of TVT™ are appropriate and acceptable for balancing success rates and complications for treating stress



incontinence. TVT is classified as an Amid Type I macroporous mesh, which is the generally accepted classification for biomaterials. The effective porosity theory adopted by plaintiffs' experts is not generally accepted in the SUI literature or by experts in the field of gynecology, urogynecology, or urology. TVT™ is often referred to as a large pore, lightweight mesh in the medical literature pertaining to SUI. Given the small 1.1 cm width of the TVT™, the mesh construction, pores, and weight are ideal for supporting the midurethra and allowing for tissue ingrowth. Any suggestion that changes would improve patient outcomes and reduce complications, while maintaining or improving clinical efficacy are unfounded and not supported by RCTs or clinical literature. Complications do not occur at an increased frequency because of the pore size or weight of TVT™.

12. All surgical procedures are associated with risks and complications. The complications associated with TVT are acceptably low. Just because a patient experiences a complication does not mean that TVT™ is defective. No device or surgical procedure is perfect, but the mesh used in TVT™ is the best studied surgical procedure for treatment of stress urinary incontinence. Complications can occur due to surgical technique and various patient factors, which can also influence wound healing complications, such as mesh exposure.
13. All surgeries have risks and surgeons must help individual patients weigh her risk profile. Mesh exposures are complications unique to synthetic midurethral slings compared to native tissue repairs and occur in approximately 2-3% of women in the first 2-years after surgery; however, most mesh complications are easy to manage and many exposures are asymptomatic requiring no intervention. Voiding dysfunction, persistent retention, and urinary tract infections are complications that are more common after bladder neck fascial slings.
14. Native tissue repairs with permanent or absorbable sutures can also result in suture exposures and erosions, which could require a re-operation or simple office excision of the exposed or eroded suture.
15. Lighter weight, larger pore meshes have not been shown to be safer or more effective than TVT™ in clinical studies or RCTs.
16. Post-operative chronic pain and dyspareunia are rare complications associated with midurethral sling and TVT™ (Schipf 2014 SGS). In a randomized trial of 565 women undergoing TVT™ or transobturator sling, only 2% of those undergoing TVT™ reported any pain beyond 6-weeks after surgery. Pelvic pain and dyspareunia are common conditions among the general population, even for women who haven't undergone pelvic surgery, and have also been reported in the medical literature for traditional procedures. (Mathias 1996, Jamieson 1996.



Francis 1961, Glatt 1990, Laumann 1999, Ozel 2005, Barber 2002). TVT has shown in studies to improve sexual function (Jha).

17. The complications, as well as the frequency and severity of those complications associated with TVT are known and acceptable to pelvic floor surgeons performing surgeries to treat stress urinary incontinence. The SGS Systematic Review shows TVT with lower rates of pelvic pain and dyspareunia compared to Burch and the Autologous Fascial Sling (Schimpf 2014).
18. TVT™ fraying is not a defect. The frayed edges may help with tissue integration and there are no clinical implications associated with mesh fraying. There are no studies that have shown an increase in adverse events due to fraying of mechanically cut mesh. The laser cut TVT-Exact also has the potential to fray. I have not seen in my clinical practice or in the literature, any clinically significant difference in complications or success rates between mechanically cut and laser cut mesh.
19. Several long-term studies on TVT™ would have been mechanically cut TVT, and they all have shown that TVT™ remains safe and effective for over 10 years. These results are consistent with Nilsson's 17-year results.
20. There is no objective clinical evidence that particle loss occurs in vivo. I have not seen particle loss in my practice in the more than 1,000 synthetic midurethral slings, I have placed, nor have I seen any medical literature showing a clinically or statistically significant increase in complications due to hypothetical particle loss.
21. TVT™ does not undergo clinically significant degradation. There is no peer-reviewed clinical literature, including randomized controlled trials, that supports the theory that TVT™ degrades, loses particles, ropes, frays or curls occur in women over time, or that there are clinically significant risks of degradation. I am not aware of any peer-reviewed published literature that shows any risks or complications associated with theoretical degradation nor am I aware of any professional organizations or content experts who have expressed a concern with degradation associated with TVT™. The clinical studies (such as Clave's study) plaintiffs' experts rely on to suggest in vivo degradation occurs with TVT are flawed and do not confirm in vivo degradation, nor do they show an increase in clinically significant complications caused by degradation, or how much degradation is required to cause harm.
22. Burch colposuspension and bladder neck fascial sling remain appropriate surgical options in carefully select women, such as those with occult stress incontinence; those undergoing concomitant urethrovaginal fistula or diverticulum; those with prior mesh complications and/or failed midurethral sling; or those who do not want mesh. The current literature supports repeat midurethral sling after a failed midurethral sling.

23. I have performed a search of the literature and have not found any clinical studies or level 1 evidence that attributes any clinically significant risks associated with mechanically cut mesh fraying, roping, curling, particle loss, or degradation; or with laser cut being stiffer and causing more erosions and exposures.
24. The biomechanical properties and foreign body reaction of Prolene have been well-studied for almost 50 years as a suture and a mesh. Polypropylene is an appropriate material for use in clean contaminated surgeries.
25. Inflammation is not a complication. Inflammation is a necessary mechanism of tissue healing. Clinical studies have shown ideal tissue reaction with TVT (Falconer 2001).
26. The FDA performed a literature review of midurethral slings and found that full-length slings, such as TVT, were safe and effective.
27. The effect of attorney advertisements has caused significant confusion among patients. Numerous patients enjoying the benefits of continence with NO adverse complications after midurethral sling seek medical consultation secondary to concerns over 'recalled mesh' after being approached by lawyers or seeing advertisements.<sup>10</sup> AUGS members have expressed their concern for their patients who are being contacted (usually by phone) by individuals unknown to them asking them personal questions about their gynecology surgery.<sup>11</sup> AUGS received 202 responses with 92% indicating that their patients had been contacted by an external source encouraging them to participate in a medical device lawsuit. The majority were contacted by phone after their surgery (96%). The caller knew the patient's name and procedure-specific information. The 2015 AUA Monograph found that, "[m]edia attention and publicly advertised personal injury lawyers' ad campaigns have led to confusion, fear, and negative perception regarding the use of synthetic material for treatment of SUI. The medical community generally has not shared the negative perception of synthetic mid urethral slings." The Monograph went on to note that:
  - One of every three women will experience Stress Urinary Incontinence (SUI) at some point during their lives. Too many of them "live with" the condition, too embarrassed to seek help or thinking that it is a "normal" part of aging and having children.

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<sup>10</sup> Perkins (2015): The Role of Mid-urethral Slings in 2014: Analysis of the Impact of Litigation on Practice. Curr Bladder Dysfunct Rep.

<sup>11</sup> Nager (2014): AUGS – Final Presidential Blog.

- SUI can interfere with quality of life. It may affect day-to-day decisions about social activities.
  - The Burch Colposuspension is a more invasive surgical procedure that has become less popular with the advent of the less invasive sling procedures.
  - Slings are the most commonly used surgery for SUI. Today, synthetic polypropylene mesh slings are the most common operation performed for SUI worldwide. One advantage of synthetic slings is a faster recovery time for patients.
  - There is support for the use of synthetic materials to treat SUI with minimal morbidity compared to alternative surgeries. There are advantages regarding surgical recovery, need for hospitalization, and reduced problems with urination. However, there are certain mesh-specific complications that can occur but in most patients the risks are considered acceptably low. These mesh-specific complications include prolonged pain (1%), vaginal exposure of the mesh (1-2%) and erosion into the urinary tract (urethra or bladder) (< 0.01%).
28. No clinical evidence exists supporting the idea that the Prolene mesh used in TVT™ is cytotoxic and causes cell death in vivo, or is associate with malignancy that causes an increase in complications or a decrease in efficacy. There are no reported cases of TVT being causally linked to any cases of cancer.
29. Retropubic midurethral slings have equivalent, if not superior, long-term success rates compared to Burch colposuspension and autologous fascial sling.
30. I have explanted various meshes as well as TVT™, and I have not seen any migrating particles or TVT meshes that were degraded based on an observation with the naked eye. If any surface cracking or alleged degradation is going to be observed, it would be misleading to suggest that one could see signs of degradation that require SEM imaging or analytical tests to visualize or confirm.
31. In my experience with implanting and explanting TVT, I have not seen loose particles, fraying, or degraded mesh. I have used both mechanically cut TVT and laser cut TVT and I have not noticed a difference with the properties of the mesh or complications. I have seen company documents that refer to laser cut meshes as being stiffer which could cause more complications, but that is not what I have seen in my clinical practice or the medical literature. I have also seen internal documents that suggest mechanically cut mesh frays, ropes, curls, and causes particle loss, but I have not seen that in my clinical practice or in the clinical literature. Nor have I seen an increase in complications in my patients or

in the clinical literature due to TVT being mechanically cut as opposed to laser cut. Further, I have also seen internal documents that suggest laser cut meshes could the mesh to lay flat and reduce retention, but I have not seen an increase in retention or meshes that aren't laid flat under the midurethra with mechanically cut TVT. Both mechanically cut and laser cut TVT meshes have the potential to fray if they are misused or stretched beyond clinically relevant forces under extreme testing; however, they function the same when used as intended in clinical use for treatment of SUI.

32. High volume surgeons have reduced complications, and implanting surgeons are more often than not informed if their patient has a complication through or referral or by reoperating on the patient (Welk 2015). In the recent Welk study, out of 59,887 women who underwent mesh based procedure for SUI, only 2.2% were treated for complications and the 10 year cumulative incidence rate was 3.29%. Welk and colleagues found that "[t]he cumulative incidence of mesh removal or revision increased from 1.2% after 1 year of follow-up to 2.5% after 10 years of follow-up. The risk of surgical revision or removal of incontinence mesh is relatively rare, but does increase with time to 2.5% after 10 years of follow-up. Patients of high volume surgeons are significantly less likely to experience complications, and women who have undergone multiple sling placements are at much higher risk of experiencing these complications." Other studies report a sling revision rate of 2.7%, with a median time of revision from the index surgery to the revision surgery of 7.8 months (Unger 2015) and 3.7% cumulative risk over 9 years (Funk 2012). Similarly, the sling complication was treated by the same implanting surgeon in 62.1% of the cases. Schimpf (2014) reported low complication rates with TVT based on a systematic review performed by the SGS. Case reports and case series, such as the Abbott 2014 case series is unreliable, biased, and should not be relied upon to extrapolate complications to an entire population given the small patient population, bias, and low level 4 case series evidence. Further, level 4 case series and case reports do not represent appropriate evidence based medicine for making clinical decisions.

#### **IX. TVT and Synthetic Midurethral Slings Have Replaced Traditional Procedures as the Gold Standard Surgical Treatment for Stress Urinary Incontinence:**

Even as early as 2002, an IUGA survey<sup>12</sup> showed that the procedure of choice for stress incontinence was TVT (48.8%), followed by Burch colposuspension (44%), and suburethral or autologous fascial slings used 3.8% as a primary procedure.

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<sup>12</sup> Davila (2002): Pelvic Floor Dysfunction Management Practice Patterns: A Survey of Members of the International Urogynecological Association [IUGA].

In a 2005 publication<sup>13</sup> analyzing practice patterns of AUGS members, the authors described a study which reported a prevalence of sexual dysfunction in 48% of patients presenting to a urogynecology clinic. Pelvic surgery may also increase this risk. Although most reports suggest improvement of sexual function following hysterectomy, there are some patients who may report negative changes postoperatively. Certain surgical repairs such as Burch bladder suspension with posterior colporrhaphy may be associated with increased rates of dyspareunia. Finally, postoperative vaginal stenosis may result from levatorplasty or aggressive trimming of the vaginal mucosa and result in dyspareunia or apareunia.

Another study from 2005<sup>14</sup> analyzed the practice patterns and determining trends of IUGA members, the authors found that “the preferred primary continence procedure was Tension Free Vaginal Tape (TVT) in one hundred and thirty four (68%) respondents. The preferred secondary continence procedure was colposuspension or Trans obturator tape in twenty-six respondents each (13%). The preferred secondary continence procedure (Table 2) was TVT in a majority (37%) followed a close second by colposuspension (34%). Pubovaginal slings, using autologous fascia and cadaveric fascia, proposed by McGuire accounted for 10% of the preferred secondary continence procedures. 96% of respondents were performing TVT. The majority of the respondents were using regional anaesthesia (45%) for performing TVT followed by local anaesthesia in 33%. General anaesthesia was being used only by 21%. A post procedure cough test was done in 60% cases. The predominant surgical procedure of choice is now TVT. This has replaced colposuspension as the primary continence surgery of choice. Since the publication of the recent NICE (National Institute of Clinical Excellence) guidelines on the surgical management of USI, both TVT and colposuspension have been identified as the gold standard surgical procedures in the management of stress incontinence. However as TVT is an easier procedure associated with less morbidity than colposuspension, so is fast becoming more popular. TVT was also more likely to be cost-effective compared to colposuspension as long as the differential inpatient length of stay for women in the TVT group was no more than one day higher than for those who underwent Colposuspension.”

A study from 2009<sup>15</sup> looking at trends in treatment of SUI from 1979-2004 found that “With the introduction of the tension-free midurethral sling in 1995, pubovaginal slings have become a common first-line outpatient treatment for SUI,” and that “The relative decline in the more traditional suburethral sling procedure (ICD-9-CM, 59.4) and retropubic urethral suspension (ICD-9- CM, 59.5) likely is due to an increase in the use of midurethral slings, replacing these traditional procedures.”

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<sup>13</sup> Pauls / Karram (2005): Practice Patterns of physician members of the American Urogynecologic Society [AUGS] regarding female sexual dysfunction: results of a national survey.

<sup>14</sup> Jha (2005): Surgical Management of Stress Urinary Incontinence: A Questionnaire Based Survey. [IUGA]

<sup>15</sup> Oliphant (2009): Trends in Stress Urinary Incontinence Inpatient Procedures in the United States, 1979-2004.

Similarly, a study from 2009<sup>16</sup> identified patterns in the surgical management of women with stress urinary incontinence in the United States from 1992 to 2001 and found that “[t]he 1990s saw a rapid shift in the surgical management of stress urinary incontinence. The rapid increase in utilization of sling procedures corresponded with a decrease in utilization of the many other available anti-incontinence procedures.”

A study from 2010<sup>17</sup> analyzing SUI procedures in Belgium from 1997-2007 found a near fourfold increase in the number of SUI procedures that coincided with the introduction of TVT in the Belgian market between 1998 and 2001. Rates of anti-incontinence surgery increased by 272% in Belgium between 1997 and 2007. “This tension-free placed mesh is relatively easy to install and as effective as the open colposuspension. It causes less morbidity compared to the colposuspension and, therefore, has become the gold standard. The tension-free sling has become very popular throughout the world.” Further, “reasons for the important rise in anti-incontinence surgical procedures may be that the tension-free procedures yield an excellent outcome, are of relatively short duration and require only a brief patient stay in the hospital. Another reason may be the easiness for the practitioner to learn the procedure.”

A 2011 study<sup>18</sup> evaluating trends in inpatient urinary incontinence surgery in the United States between 1998 to 2007 found that the “total number of SUI surgeries performed during this 10-year period was 759,821. The annual number of procedures increased from 37,953 in 1998 to 94,910 in 2007. The type of SUI surgery performed also changed ( $p < 0.001$ ). In 1998, retropubic suspensions represented 52.3%, decreasing to 13.8% in 2007. “Other repair of SUI” (ICD-9 59.79) comprised 22.4% in 1998, increasing to 75.2% in 2007, likely representing midurethral slings. Although numerous incontinence surgeries have been variably popular in recent decades, retropubic colposuspensions and traditional bladder neck slings have proven long-term efficacy. However, these two procedures are not minimally invasive and require an abdominal incision. The midurethral mesh sling, a minimally invasive procedure that can be performed quickly with comparable outcomes to the Burch colposuspension, is now considered by many in the USA to be the new gold standard since its introduction in the USA 10 years ago. In 1998, the most common procedure was retropubic urethral suspension (52.3%) followed by “other repair of SUI” (22.4%) (Table 2). This finding had reversed by 2007, when the most common procedure was “other repair of SUI” (75.2%) followed by retropubic procedures (13.8%) (“other repair of SUI” represents the ICD-9 procedure code 59.79) (Table 2 and Fig. 1). Suprapubic slings remained the third most common procedure at 15.8% in 1998 and 8.2% in 2007.

<sup>16</sup> Anger (2009): Trends in the Surgical Management of Stress Urinary Incontinence among Female Medicare Beneficiaries [1992-2001].

<sup>17</sup> Cammu (2010): Dramatic increase (1997-2007) in the number of procedures for stress urinary incontinence in Belgium.

<sup>18</sup> Wu (2011): Trends in inpatient urinary incontinence surgery in the USA, 1998-2007.

A 2012 study<sup>19</sup> analyzing SUI surgery data from 2000 to 2009 found that there was a dramatic increase in slings, with a corresponding decrease in Burch procedures from 2000 to 2009. Other SUI surgeries had lower rates. Thus, in 2009, slings represented 89.1% of all SUI procedures followed by collagen with 4.0%, Burch with 3.8%, and all other SUI surgeries combined with 3.0%.

An 11 center RCT from 2012<sup>20</sup> found that “approximately 93% of the participants in both groups received a transobturator or retropubic midurethral sling, and midurethral slings are routinely used in patients with either stress incontinence or both stress and urge (mixed) incontinence. The surgical treatments that were performed in the urodynamic-testing and evaluation-only groups, respectively, were as follows: retropubic midurethral sling in 64.7% and 64.6%, transobturator midurethral sling in 29.0% and 28.1%, mini-sling in 2.0% and 1.4%, traditional sling in 3.4% and 4.9%, retropubic urethropexy in 0.0% and 0.7%, and urethral-bulking injection in 1.0% and 0.4%.”

A study from 2013<sup>21</sup> analyzing a total of 6355 nonpediatric urologists applied for certification or recertification between 2003 and 2012 found that “Two-thirds (4185) reported performing any procedures for female incontinence. Procedures sharply increased from 4632 in 2003 to 7548 in 2004, then remained relatively stable between 2005 and 2012 (range, 8014-10,238 cases). Traditional procedures decreased from 17% of female incontinence procedures in 2003 to 5% in 2004 to <1% since 2010 (P <.0005). Midurethral sling procedures have risen sharply from 3210 procedures in 2003 to 7200 in 2012 (P <.0005).” The authors concluded that “Midurethral slings have been widely adopted by urologists over the last decade. Increase in sling usage coincided with a drastic decline in traditional repairs, implying that the newer midurethral slings were replacing these traditional procedures for the treatment of female incontinence.” “The medical, psychological, social, and economic burden of female stress urinary incontinence (SUI) is significant. The more minimally invasive options have gained popularity because of their procedural ease and likely decreased rates of complications. With the apparent proliferation of midurethral slings, we sought to determine the changes in practice pattern of urologists surgically managing SUI in the United States. We conducted an analysis of annual case logs submitted to the American Board of Urology (ABU) for certification and recertification between 2003 and 2012. Of all urologists treating female incontinence, 3878 (93%) reported any use of slings and 2216 (53%) reported using slings exclusively. The present study, which evaluates data from the ABU, shows that midurethral slings and urethral bulking agents are the only procedures performed currently for female SUI, with 5 times as many midurethral slings performed as urethral bulking agents. The treatment for female SUI has evolved over

<sup>19</sup> Funk (2012): Trends in the Surgical Management of Stress Urinary Incontinence [United States].

<sup>20</sup> Nager (2012): A Randomized Trial of Urodynamic Testing before Stress-Incontinence Surgery.

<sup>21</sup> Chughtai (2013): Midurethral Sling Is the Dominant Procedure For Female Stress Urinary Incontinence: Analysis of Case Logs From Certifying American Urologists.



the past decade. The overall number of midurethral slings cases performed for female SUI has doubled. An increased awareness of the problem, an aging population, and the proliferation of synthetic midurethral slings all likely contributed to this trend. Concurrently, there has been a decline in the number of traditional repairs reflecting current urologic training.”

Another study from 2011<sup>22</sup> evaluated AUGS Members’ use of synthetic mesh after the 2011 FDA Public Health Notification. The authors found that “Little change in the use of synthetic or biologic slings was seen after the 2011 FDA safety update. Virtually all members continue to use synthetic mesh for slings, including 90% of members that use mesh in 90% to 100% of sling cases, whereas only 10% use biologic grafts for slings. Table 3: Mesh Sling: 93% (453) – Same use (still using – no change in practice).”

Additionally, a 2013 study<sup>23</sup> compared the effectiveness of mesh versus non-mesh sling surgery in Medicare patients as measured by the frequency of complications with 1 year. They identified 6,698 Medicare beneficiaries who underwent mesh sling procedures and 445 Medicare beneficiaries who underwent nonmesh sling procedures. “The overall frequency of complications was similar between the two groups at 69.8% and 72.6% in the mesh and nonmesh groups, respectively. Patients undergoing mesh procedures were less likely than patients undergoing nonmesh procedures to require management for bladder outlet obstruction... and were less likely to have a subsequent sling removal and revision or urethrolisis. Frequencies of most complications were similar regardless of the use of mesh except for the management of bladder outlet obstruction. Surgical technology has evolved tremendously over the past two decades, resulting in the development of procedures with decreased morbidity and faster recovery. These changes have facilitated the migration of select procedures from the hospital outpatient department to the ambulatory surgery center, where they typically can be performed at a lower cost per episode. Anti-incontinence surgery is a perfect example of this shift. With the development of polypropylene mesh for use in midurethral slings in the mid-1990s, rates of sling procedures have dramatically increased, replacing older, more invasive inpatient procedures such as the Burch colposuspension. Between 2006 and 2008, 12,707 slings surgeries were performed, and of these patients, 6,698 (93.8%) and 445 (6.2%) women had procedures using mesh and nonmesh materials, respectively. Table 3: Complications of Mesh and Nonmesh Slings Within 1 Year of Surgery. Any complication: Mesh = 69.8%; Nonmesh = 72.6%; New diagnosis of pelvic pain: Mesh = 6.4%; Nonmesh = 6.2%. First complications occurring within 1 year of hospital-based outpatient sling placement were relatively common regardless of whether mesh was used, although the majority of these were minor. In fact, patients undergoing nonmesh procedures had a less favorable complication profile

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<sup>22</sup> Clemons (2013): Impact of the 2011 FDA Transvaginal Mesh Safety Update on AUGS Members’ Use of Synthetic Mesh and Biologic Grafts in Pelvic Reconstructive Surgery.

<sup>23</sup> Suskind (2013): Effectiveness of Mesh Compared with Nonmesh Sling Surgery in Medicare Beneficiaries.



in that they were more likely to require a subsequent intervention for bladder outlet obstruction, including sling removal and revision or urethrolisis procedures. Our findings are also consistent with the American Urological Association Guidelines that suggest that synthetic slings have similar efficacy and less morbidity than nonmesh surgical techniques.”

A 2013 study<sup>24</sup> evaluating trends in the surgical management of SUI from 2002 to 2007 found that surgical management of women with SUI shifted toward a dominance of procedures performed in ambulatory surgery centers from 2002 to 2007, although the overall number of procedures remained stable. Slings remained the dominant surgical procedure, followed by injectable bulking agents, both of which are easily performed in outpatient settings. The past decades have witnessed a shift in the surgical management of SUI toward a dominance of sling procedures. As part of the Urologic Diseases in America Project, we previously analyzed data from Medicare beneficiaries from 1992 to 2001 and found rapid shifts in surgical procedures for female SUI. In 1992, urethropexy (Burch, Marshall-Marchetti-Krantz) was the most commonly performed procedure. However, it was surpassed by the sling and the suburethral bulking procedures by 2001. Similar declines were seen with urethropexy and needle suspensions. Conversely, we demonstrated an increase in slings from among the least commonly performed procedures in 1992 to the most commonly performed procedure in 2001.”

A study from 2014<sup>25</sup> compared the surgical trends for primary Sui from 2006-2010 vs. 1997-2005 and found that “the follow-up study, midurethral sling (MUS) application increased significantly from 53.09 % in 2006 to 78.74 % in 2010. It was associated concomitantly with a decrease in retropubic urethropexy (RPU) from 29.68 % to 12.99 %, and pubovaginal sling treatment (PVS) from 9.33 % to 3.46 %. MUS was most commonly used among all patients’ and surgeons’ age groups, and different accreditation hospital levels. Of all surgeries 12,351 (81.8 %) were performed by gynecologists, whilst 2,649 (17.5 %) were performed by urologists. Nevertheless, a comparison between the practice patterns of surgeons with different specialties reveals that MUS was the most commonly adopted surgery by both gynecologists (71.38 %) and urologists (57.91 %). During time-frame comparison, MUS increased 2.7 times (68.79 % vs 25.25 %), accompanied by a decrease in RPU 2.3 times (46.84 % vs 20.18 %) and a decrease in PVS 2.8 times (15.96 % vs 5.66 %). MUS significantly increased up to 78 % in 2010, concomitantly decreasing the numbers of RPU and PVS considerably. In a recent review by Cox et al., MUS has been demonstrated to be just as effective as these traditional procedures, e.g., RPU and PVS, but with less associated morbidity, based on randomized controlled trials. Thus, MUS is granted as a new “gold standard” first-line

<sup>24</sup> Rogo-Gupta (2013): Trends in the Surgical Management of Stress Urinary Incontinence Among Female Medicare Beneficiaries, 2002-2007.

<sup>25</sup> Wu (2014): The surgical trends and time-frame comparison of primary surgery for stress urinary incontinence, 2006-2010 vs 1997-2005: a population-based nation-wide follow-up descriptive study.

surgical treatment for women with uncomplicated SUI. The choice of surgical procedures may more or less depend on the surgeons' preferences for the treatment options. As for surgeons' age, MUS was more commonly used by surgeons aged <50 years, while PVS and periurethral injection were more commonly performed by surgeons aged ≥50 years."

Another study from 2014<sup>26</sup> evaluating the current status of SUI treatments in Korea found that the number of surgical cases decreased continuously from 2008 to 2011. However, the number of transvaginal surgeries using a midurethral sling (R3565) increased continuously. Only a few of the SUI surgeries involved the Burch operation and injection therapy (Table 1). The sling procedure has become the most common SUI surgery technique. Table 1: The number of surgical cases according to the year of surgery. Surgeries in 2008 (n = 42,195) were: Synthetic MUS = 39,516 (96%) Autologous fascial sling = 1,358 (3.3%); Burch colposuspension = 103 (0.2%). Surgeries in 2009 (n = 42,166) were: Synthetic MUS = 40,684 (98.6%); Autologous fascial sling = 547 (1.3%); and Burch colposuspension = 47 (0.1%). Surgeries in 2010 (n = 34,787) included: Synthetic MUS = 33,693 (99.3%); Autologous fascial sling = 231 (0.6%); Burch colposuspension = 29 (0.1%). Surgeries in 2011 (n = 33,173) were: Synthetic MUS = 32,166 (99.3%); Autologous fascial sling = 227 (0.6%); and Burch colposuspension = 66 (0.2%).

A study from 2015<sup>27</sup> evaluating the IUGA members' practice patterns showed that the preferred method of treatment for SUI is the midurethral sling, regardless of prior treatments, concomitant surgeries, or examination findings. "Synthetic midurethral slings are predominant in the current treatment of SUI." "The treatment of stress incontinence has shifted in recent years, with the initial survey showing a predilection for the Burch colposuspension as a primary and secondary surgical treatment for normal pressure urethral SUI (44 and 41%), while the current survey revealed that 2% of respondents were performing the Burch procedure as a primary SUI treatment and 11% of respondents were using it as a secondary treatment." TVT is the preferred treatment for patients with ISD.

Pelvic organ prolapse and SUI are different health conditions. Surgeries that use mesh to treat these conditions have their own unique risks and benefits.<sup>28</sup> All surgeries carry a risk of side effects. The FDA found that long-lasting side effects from treating SUI with mesh seem to be rare. For patients who choose to have surgery, mesh sling surgery is the most common procedure used. It is a less invasive surgery, and patients tend to recover quicker than with the alternative surgeries to correct SUI. (These alternatives

<sup>26</sup> Cho (2014): Nationwide Database of Surgical Treatment Pattern for Patients with Stress Urinary Incontinence in Korea.

<sup>27</sup> Ghoniem (2015): Female pelvic medicine and reconstructive surgery practice patterns: IUGA member survey.

<sup>28</sup> Winters: A Conversation with Dr. Winters [President of SUFU]: Questions About "Vaginal Mesh" for SUI Repair. Urology Care Foundation (AUA).

are slings using patients' own tissues and bladder suspension procedures.) The AUA's guidelines list mid-urethral, mesh slings, as a "standard" treatment for SUI. The AUA points to a large number of scientific studies that support the use of mesh slings to treat SUI.

The midurethral sling remains the gold standard surgical repair for treating SUI.<sup>29</sup> "Specifically MUS, which are the predominant SUI surgical procedure and the clear standard of care – remain in the surgeon's armamentarium after the July 2011 FDA safety warning. A PubMed search of "tension-free vaginal tape" reveals more than 2,000 publications. Midurethral slings and pubovaginal slings had similar cure rates. Pubovaginal slings, however, had more postoperative lower urinary tract symptoms and a higher reoperation rate. Pubovaginal slings require an 8-cm lower-abdominal incision, general or regional anesthesia, and hospitalization (usually). They also have higher risks of intraoperative bleeding and wound complications (including incisional hernias) than MUS. By contrast, MUS require 3 small 1-cm incisions and can be performed on an outpatient basis with local anesthesia and sedation. Postoperative recovery is significantly easier and shorter with MUS than with pubovaginal slings. In this century, the full-length MUS procedures are the predominant SUI surgical procedure and the clear standard of care. Studies have not demonstrated common or significant vaginal pain or pain with intercourse after MUS. I urge you to not replace on a widespread basis the most studied, safe, and successful treatment for SUI with a procedure that is considerably more invasive and complicated and can be more painful and require a longer recovery. We all must do our best to clear up the confusion created by misleading television advertisements by law firms. Full-length synthetic midurethral slings remain the current standard of care for stress incontinence surgery."

A 2010 review in the New England Journal of Medicine described that, "[u]ntil recently, the reference standards for incontinence surgery included the Burch retropubic urethropexy and the suburethral fascial sling; however, both require an abdominal incision and are associated with substantial postoperative recovery time and complications.<sup>30</sup> The fascial sling is also with higher rates of post-operative complications. Many women are reluctant to undergo either procedure because of the strain that hospitalization and recovery places on their families and jobs. In 1996, Ulmsten et al introduced a synthetic midurethral sling, the tension-free vaginal tape, which could be inserted by means of a minimally invasive surgical procedure. Incisions are small, most procedures are performed on an outpatient basis, and postoperative recovery is rapid."

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<sup>29</sup> Nager (2012): Synthetic full-length midurethral slings remain the standard of care for SUI surgery. OBGManagement

<sup>30</sup> Rogers (2010): What's Best in the Treatment of Stress Urinary Incontinence? New England Journal of Medicine.

In 2012, Lee and colleagues<sup>31</sup> found that midurethral sling (MUS) is the gold standard for stress urinary incontinence (SUI) in the index patient, with equivalent outcomes and minimal adverse events in comparison with traditional SUI procedures. The midurethral sling (MUS) is now the most commonly performed surgical treatment for stress urinary incontinence (SUI). It is considered the gold standard for patients with genuine SUI. Encouraged by the excellent outcomes and low morbidity in these index patients, clinicians have extended the use of the MUS to treat SUI in more complex situations, such as recurrent SUI, mixed urinary incontinence (MUI), and SUI in the elderly or obese. In 1997, the AUA Female Stress Incontinence Clinical Guidelines Panel concluded that the retropubic suspensions and pubovaginal sling (PVS) were the most effective treatments for SUI, reflecting the widespread sentiment that these procedures represented the gold standard at that time. Only 2 years earlier, Ulmsten and Petros first described the tension-free vaginal tape (TVT), a retropubic midurethral synthetic sling that was considerably less invasive with high short-term success rates. Because of the relative ease of performance and very good initial results, it quickly became one of the most commonly performed procedures and inspired the development of various other MUSs. Several RCTs have confirmed their findings, culminating in the most recent meta-analysis by Novara and colleagues, which found that the MUS is more effective than the Burch colposuspension and equally as effective as the PVS in achieving objective cure of SUI. Thus, the MUS has effectively been established as the new gold standard for surgical treatment of SUI. Overall summary of Cochrane meta-analysis for retropubic and transobturator slings. For retropubic versus transobturator approach: retropubic slings have a slightly higher objective cure rate (88% vs 84%), but there is no difference in subjective cure rate (83% for both groups in the Cochrane meta-analysis). The Pubovaginal Sling has traditionally been identified as the procedure of choice after failed incontinence surgery based on its superior efficacy over colposuspension, and in this setting reported cure and improvement rates have ranged from 59% to 86%, but data have been lacking on its use in the MUS era. Midurethral slings have become the most commonly performed procedures for stress urinary incontinence in North America. Management of vaginal erosions can be straight forward and simple. The midurethral sling will continue to be extensively utilized in the foreseeable future. Surgical choice between retropubic and obturator versions is driven by surgical experience and patient selection.

A 2012 review in OBGManagement<sup>32</sup> noted that “almost all surgical procedures for stress urinary incontinence performed today involve placement of a retropubic or transobturator midurethral synthetic sling. Today, virtually all of these operations have been replaced in general practice by retropubic or transobturator (TOT) midurethral synthetic slings. Although Burch colposuspension and the pubovaginal fascial sling procedure are effective for both primary and recurrent SUI, they are more invasive than midurethral slings, cause more voiding dysfunction, and have significantly longer

<sup>31</sup> Lee (2012): Midurethral Slings for All Stress Incontinence: A Urology Perspective

<sup>32</sup> Walters (2012): Which Sling for Which SUI Patient? OBGManagement: Surgical Technique.

recovery times, making them less attractive for most primary and recurrent cases of SUI. The evolution of SUI surgeries has shifted so far toward midurethral slings that Burch colposuspension and the pubovaginal sling procedure are rarely performed or taught in obstetrics and gynecology or urology residency programs. Compared with synthetic slings, fascial slings are effective but take longer to place and have a higher rate of surgical morbidity and more postoperative voiding dysfunction. They are now mostly indicated for complex recurrent SUI, usually managed by specialists in female pelvic medicine and reconstructive surgery. Current slings are lightweight polypropylene mesh. Most slings today are tension-free midurethral slings consisting of synthetic, large-pore polypropylene mesh. Mesh exposures occur with similar frequency for the different sling types as long as large-pore lightweight polypropylene is used. Dehiscence of the suburethral incision (mesh exposure) is uncommon with midurethral slings, occurring in 1% to 2% of patients. Dehiscence can be managed with estrogen cream or trimming of the exposed portion of the sling in the office.

A 2013 review by Cox<sup>33</sup> reviewed a number of Cochrane Reviews and found that “the traditional gold standards of Burch retropubic colposuspension and pubovaginal slings are still appropriate treatment options for some patients, but randomized controlled trials have demonstrated that synthetic midurethral slings are just as effective as these traditional procedures but with less associated morbidity. Thus, midurethral slings— inserted via a retropubic or transobturator approach—have become the new gold standard first-line surgical treatment for women with uncomplicated SUI.” The review noted that retropubic MUSs are effective for patients with mixed urinary incontinence. “Based on the literature a new gold standard first-line surgical treatment for women with SUI is the synthetic midurethral sling inserted through a retropubic or transobturator approach.” “Synthetic midurethral sling procedures were first developed by Ulmsten in 1995, since which time they have become the most commonly performed procedure for female SUI. The reasons for this are multiple: the procedures are performed relatively quickly, are easy to learn, and have acceptable rates of morbidity. More importantly, there are now long-term data to show that they compare favorably to the traditional methods of surgical repair for SUI detailed above.”

#### **X. The Benefits of TVT Outweigh the Risks of Harm:**

The AUA Position Statement approved in 2011 and revised in 2013 noted the following about the safety profile and utility of synthetic midurethral slings such as TVT:

- Suburethral synthetic polypropylene mesh sling placement is the most common surgery currently performed for SUI. Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI, with minimal morbidity compared with alternative surgeries. Advantages include

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<sup>33</sup> Cox (2013): Surgical Management of Female SUI: Is there a Gold Standard?

shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, and reduced voiding dysfunction.

- Mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low. Furthermore, it is important to recognize that many sling-related complications are not unique to mesh surgeries and are known to occur with non-mesh sling procedures as well. It is the AUA's opinion that any restriction of the use of synthetic polypropylene mesh suburethral slings would be a disservice to women who choose surgical correction of SUI.
- Additionally, both the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) and the AUA support the use of multi-incision monofilament midurethral slings for the treatment of SUI in properly selected patients who are appropriately counseled regarding this surgical procedure by surgeons who are trained in the placement of such devices, as well as the recognition and management of potential complications associated with their use.
- Multiple case series and randomized controlled trials attest to the efficacy of synthetic polypropylene mesh slings at 5-10 years. This efficacy is equivalent or superior to other surgical techniques. There is no significant increase in adverse events observed over this period of followup. Based on these data, the AUA Guideline for the Surgical Management of Stress Urinary Incontinence (2009) concluded that synthetic slings are an appropriate treatment choice for women with stress incontinence, with similar efficacy but less morbidity than conventional nonmesh sling techniques.

AUGS (with over 1,700 members) and SUFU (with over 500 members) adopted a joint position statement in 2014 highlighting the following about the safety and efficacy of midurethral slings:

- The polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women.
- Developed in the early 1990's, midurethral slings (MUS) treat stress urinary incontinence (SUI) in a minimally invasive, generally outpatient procedure.
- Polypropylene material is safe and effective as a surgical implant. Polypropylene material has been used in most surgical specialties (including general surgery, cardiovascular surgery, transplant surgery, ophthalmology, otolaryngology, gynecology, and urology) for over five decades, in millions of patients in the US and the world (personal communication with manufacturers of polypropylene suture and mesh). As an isolated thread, polypropylene is a widely used and



durable suture material employed in a broad range of sizes and applications. As a knitted material, polypropylene mesh is the consensus graft material for augmenting hernia repairs in a number of areas in the human body and has significantly and favorably impacted the field of hernia surgery. As a knitted implant for the surgical treatment of SUI, macroporous, monofilament, light weight polypropylene has demonstrated long term durability, safety, and efficacy up to 17 years. [Referencing Nilsson's 17 year TVT study].

- The monofilament polypropylene mesh MUS is the most extensively studied anti-incontinence procedure in history. A broad evidence base including high quality scientific papers in medical journals in the US and the world supports the use of the MUS as a treatment for SUI. There are greater than 2000 publications in the scientific literature describing the MUS in the treatment of SUI. These studies include the highest level of scientific evidence in the peer reviewed scientific literature. The MUS has been studied in virtually all types of patients, with and without comorbidities, and all types of SUI. Multiple randomized, controlled trials comparing types of MUS procedures, as well as comparing the MUS to other established non-mesh SUI procedures, have consistently demonstrated its clinical effectiveness and patient satisfaction. Among historical SUI procedures, the MUS has been studied as long in follow-up after implantation as any other procedure and has demonstrated superior safety and efficacy. No other surgical treatment for SUI before or since has been subject to such extensive investigation.
- Polypropylene mesh midurethral slings are the standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition for our patients. Since the publication of numerous level one randomized comparative trials, the MUS has become the most common surgical procedure for the treatment of SUI in the US and the developed world. This procedure has essentially replaced open and transvaginal suspension surgeries for uncomplicated SUI. There have been over 100 surgical procedures developed for the management of SUI and there is now adequate evidence that the MUS is associated with less pain, shorter hospitalization, faster return to usual activities, and reduced costs as compared to historic options that have been used to treat SUI over the past century. Full-length midurethral slings, both retropubic and transobturator, have been extensively studied, are safe and effective relative to other treatment options and remain the leading treatment option and current gold standard for stress incontinence surgery. Over 3 million MUS have been placed worldwide and a recent survey indicates that these procedures are used by > 99% of AUGS members.

AUGS and SUFU also issued Frequently Asked Questions for Providers and Patients to convey the following information about Midurethral Slings:

- A broad evidence base including high quality scientific papers in medical journals in the US and the world supports the use of mid-urethral slings as a treatment for SUI. There are greater than 2000 publications in the scientific literature describing mid-urethral slings in the treatment of SUI... Numerous randomized, controlled trials comparing types of midurethral slings, as well as comparing MUS to other established SUI procedures, have consistently demonstrated its clinical effectiveness and patient satisfaction. Among historical SUI procedures, the MUS has been studied as long in follow-up after implantation as any other procedure and has demonstrated superior safety and efficacy. This includes a recent 17 year follow-up study. No other surgical treatment for SUI before or since has been subject to such extensive investigation.
- The MUS is the most studied anti-incontinence procedure in medical history. Furthermore, it is likely that more individuals have undergone this surgical procedure for the treatment of SUI than any other. The difficulties and complications associated with mid-urethral slings are similar in character to that seen with non-mesh procedures (bladder outlet obstruction, urinary tract injury, dyspareunia, pain, etc.) with the exception of vaginal mesh exposure and mesh perforations into the urinary tract.
- Currently available mid-urethral slings are composed of macroporous, knitted, monofilament polypropylene, sometimes known as "Type I" meshes.... Polypropylene material has been used in most surgical specialties (including general surgery, cardiovascular surgery, transplant surgery, ophthalmology, otolaryngology, gynecology, and urology) for over five decades, in millions of patients in the US and the world.... As an implant for the surgical treatment of SUI, macroporous, monofilament polypropylene has demonstrated long-term durability, safety, and efficacy for up to 17 years [Nilsson's 17 year study].
- All midurethral slings available in the US are made of polypropylene knitted into a macroporous mesh.
- Does the MUS mesh made of polypropylene degrade over time? Polypropylene is a stable and well-accepted biomaterial with a history of over five decades of use in mesh implants. In recent years, concerns regarding implanted polypropylene degradation have been raised as a result of very high magnification images that show portions of some explanted synthetic meshes with "cracked" surfaces. These surface changes were further hypothesized to lead to adverse clinical outcomes, though this is not supported by the extensive peer-reviewed literature related to polypropylene mesh repairs. Prospective studies have followed patients with implanted mid-urethral slings for 17 years and show excellent durability and safety of the procedure.



- Two large government funded studies have evaluated the mid-urethral sling's safety and efficacy – both found the procedure to have a low complication rate and a high success rate. Other large scientific studies from around the world have supported the safety and efficacy of the mid-urethral sling.
- A peer-reviewed scientific article reported on the safety outcomes of the mid-urethral sling in Sweden over a 17 year period. It found a high satisfaction rate and no serious long-term adverse events related to the mid-urethral sling.
- Alternative surgical treatment options to the mid-urethral sling have been performed by surgeons for over 100 years.... In general however, the mid-urethral sling has been found to be as or more effective than any of these procedures and is as durable (the surgery maintains its favorable effects over a longer period of time). In addition, the pain related to the procedure, the time required to recover from the surgery, and time to return to normal activities including work is less for the mid-urethral sling than for any of these surgical procedures.
- There is no evidence that any women have developed cancer as a result of a mid-urethral sling.

IUGA approved a similar position statement in 2014 describing the safety and efficacy of midurethral slings:

- Stress urinary incontinence is a common, burdensome and costly condition for women with a negative impact on quality of life.
- Mid-urethral slings are minimally invasive procedures developed in Europe in the 1990s to treat female stress urinary incontinence. These slings are narrow, synthetic polypropylene tapes that are surgically placed beneath the middle part of the urethra (water pipe) to provide dynamic support to stop leakage from the bladder. They have been shown to be as effective as more invasive traditional surgery with major advantages of shorter operating and admission times, and a quicker return to normal activities together with lower rates of complications. This has resulted in MUS becoming the operation of choice in Europe, Asia, South America, South Africa, Australasia and North America for treatment of SUI with several million procedures performed worldwide.
- There is robust evidence to support the use of MUS from over 2,000 publications making this treatment the most extensively reviewed and evaluated procedure for female stress urinary incontinence now in use. These scientific publications studied all types of patients, including those with co-morbidities such as prolapse, obesity and other types of bladder dysfunction. It is, however, acknowledged that any operation can cause complications. For MUS these include bleeding, damage to the bladder and bowel, voiding difficulty, tape

exposure and pelvic pain; all of these may require repeat surgery but this is uncommon. Nevertheless, the results of a recent large multi-centre trial have confirmed excellent outcomes and a low rate of complications to be expected after treatment with MUS. Additionally, long term effectiveness of up to 80% has been demonstrated in studies including one which has followed up a small group of patients for 17 years.

- As a result, IUGA supports the use of monofilament polypropylene mid-urethral slings for the surgical treatment of female stress urinary incontinence.

Furthermore, IUGA also published guidelines for research and clinical practice in 2008 noting the complications that are related to surgical procedures for SUI:

- Complications listed below related to SUI surgical procedures can potentially involve any of the organs of the pelvis include: Bladder injuries, Urethral injuries, Ureteral injuries, Intestinal injuries, Erosions, Hemorrhage, Fistulae, Prolapse, Voiding dysfunction, Postoperative OAB, ISD, Recurrent incontinence, Dyspareunia, and Pain.
- Intravesical sutures have been reported in almost all SUI surgical procedures. These patients often present with bladder or pelvic pain, frequency, urinary tract infection, or recurrent incontinence.
- Miscellaneous complications reported after the Burch procedure, include massive hemorrhage requiring transfusion, hematoma, bladder injuries diagnosed intraoperatively and postoperatively, ureteral kinking, urinary retention, wound infection, pelvic abscess, UTI, and DVT.
- Voiding dysfunction such as frequency, nocturia, urgency with and without incontinence, hesitancy, retention, incomplete emptying, and recurrent urinary tract infections have been reported after all anti-incontinence procedures. Voiding dysfunction after retropubic colposuspension and mid-urethral sling procedures is usually transient and resolves postoperatively [204, 205]. The incidence of de novo detrusor overactivity and urge urinary incontinence varies depending upon the anti-incontinence procedure with rates as high as 33%. Comparing retropubic vs TO slings, the incidence of urge urinary incontinence and detrusor overactivity rates are lower after TO slings.
- It is clear, however, that after all anti-incontinence surgeries, erosion and migration of suture material, bolsters, supporting tacks, and synthetic mesh material can occur.
- The type of mesh material used in mid-urethral slings and prolapse surgery is of importance as some materials demonstrate higher erosion and extrusion rates than others. Higher rates are reported with synthetic mesh that is woven with

small pore size, as macrophage migration to deposit collagen and engulf bacteria is hindered (e.g., ObTape and GoreTex). Fortunately, these materials have been replaced with loosely knitted, macroporous (>75 µm), monofilament polypropylene material with lower complication rates. Mesh extrusion is usually treated with local excision in the office setting.

Australian and New Zealand societies endorsed the synthetic midurethral sling as well in a 2014 position statement from RANZOG and USGA:

- In Australia, the midurethral sling has been the operation of choice to treat female SUI since 2004. RANZCOG and UGSA support the use of monofilament polypropylene mid-urethral sling for surgical treatment of female stress urinary incontinence.

In a 2013 Position Statement related to meshes for pelvic organ prolapse, AUGS clarified that “Full-length midurethral slings, both retropubic and transobturator, have been extensively studied, are safe and effective relative to other treatment options and remain the leading treatment option and current gold standard of care for stress incontinence surgery.”

The National Institute of Health Care and Excellence set forth criteria for treating stress urinary incontinence in the 2013 Guideline, including:

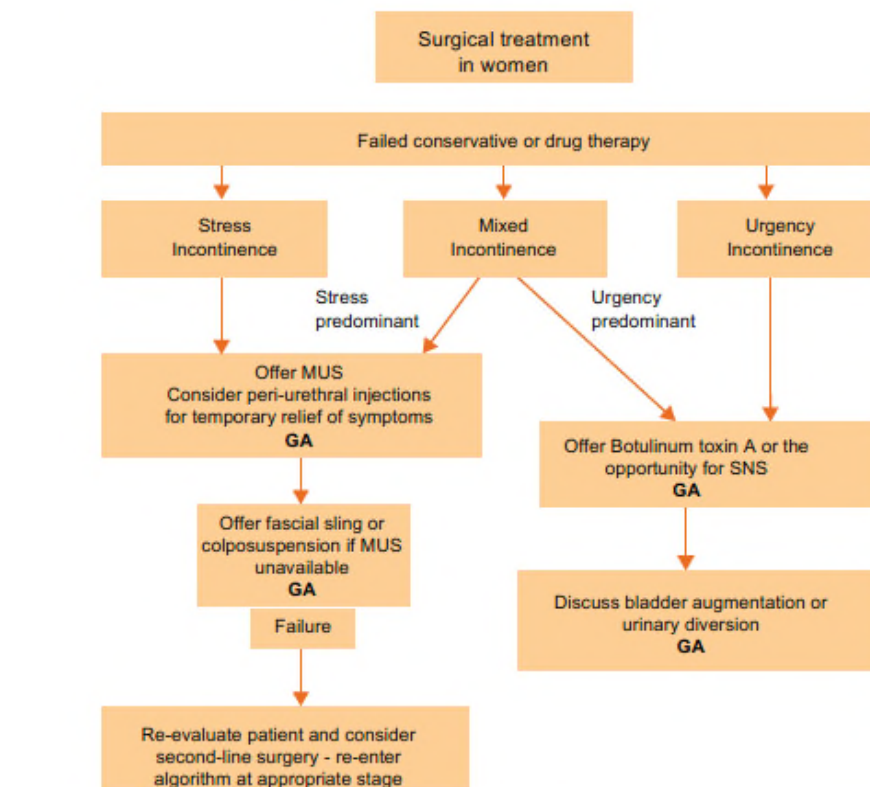
- Section 1.10.2: If conservative management for SUI has failed, offer: synthetic mid-urethral tape; open colposuspension; autologous rectus fascial sling.
- Section 1.10.3: Synthetic tapes: When offering a synthetic mid-urethral tape procedure, surgeons should: use procedures and devices for which there is currently high quality evidence of safety and efficacy [Footnote 11: The guideline only recommends the use of tapes with prove efficacy based on robust RCT evidence... TVT for retropubic approach; TVT-O for an “inside-out” transobturator approach....
- Section 1.10.9: Colposuspension. Do not offer laparoscopic colposuspension as a routine procedure for the treatment of stress UI in women.
- Section 1.10.10: Biological Slings: Do not offer anterior colporrhaphy, needle suspensions, paravaginal defect repair and the Marshall-Marchetti-Krantz procedure for the treatment of stress UI.

The European Association of Urology’s 2012 Guidelines for treating urinary incontinence found that:

- The effectiveness of colposuspension deteriorates over 5 yr, and there is a higher rate of genitourinary prolapse than with other operations. Autologous fascial sling has a higher risk of operative complications than open colposuspension, particularly voiding dysfunction and postoperative urinary tract infection (UTI).

- There has been a rapid adoption of midurethral synthetic sling insertion as the first-line surgical option for SUI because it is effective, it is less invasive, and patients recover more quickly.
- Midurethral sling insertion was associated with a lower rate of new symptoms of urgency and voiding dysfunction compared with colposuspension.
- Recommendations:
  - o Offer midurethral sling to women with uncomplicated stress urinary incontinence as the initial surgical intervention whenever available.
  - o Offer colposuspension (open or laparoscopic) or autologous fascial sling to women with stress urinary incontinence if midurethral sling cannot be considered.
  - o Warn women undergoing autologous fascial sling that there is a high risk of voiding difficulty and the need to perform clean intermittent self-catheterization; ensure they are willing and able to do so.

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The AUA Guideline for treating incontinence noted in 1997 that “Surgeons now recognize the importance of not making slings overly tight, because of the relationship between excessive tension and complications.” Additional updates occurred in 2009 and 2012. The AUA Panel Members performed a meta-analysis of the literature, with updates in 2009 and 2012, and determined that:

- Surgeons should take these considerations into account, together with their own areas and levels of expertise and their own previous treatment results, when counseling patients regarding choice of procedure.
- Stress urinary incontinence (SUI) has a significant impact on the quality of life for many women... Many women in the United States (U.S.) elect to have a surgical procedure for management of their SUI symptoms each year.
- The midurethral slings had an efficacy comparable to autologous slings in the surgical treatment of SUI.
- There are complications that may occur that are unique to specific mesh materials; however, these complications appear to be rare. Intraoperative use of cystoscopy can be performed to minimize the risk of urinary tract injury or erosion.
  - o Table 1: Cure Rates:
    - Burch at 12-23 mo = 81%; at 24-47 mo = 76%; at  $\geq 48$  mo = 73%
    - AFS at 12-23 mo = 90%; at 24-47 mo = 81%; at  $\geq 48$  mo = 82%
    - MUS 12-23 mo = 84%; at 24-47 mo = 81%; at  $\geq 48$  mo = 84%
  - o Table 3: De novo urge incontinence:
    - Burch 8%
    - AFS 9%
    - MUS 6%
  - o Table 4: Retention:
    - Burch 3%
    - AFS 8%
    - MUS 3%
- Appendix A11:
  - o Burch:
    - Pain = 6%
    - Sexual Dysfunction = 3%
    - Voiding Dysfunction = 10%
  - o Autologous Fascial Sling:
    - Pain = 10%
    - Sexual Dysfunction = 8%

- Voiding Dysfunction = \* (only case reports of this complication exist, and data are insufficient to estimate the frequency).
- MUS:
  - Pain = 1%
  - Sexual Dysfunction = 0%
  - Voiding Dysfunction = 2%

The International Continence Society (ICS) has also issues a Fact Sheet on Urinary Incontinence, which includes the following:

- Definitive therapy for SUI is surgical and involves restoring urethral support through use of a sling. Worldwide, midurethral slings comprised of synthetic mesh have become the treatment of choice for SUI. Long-term data are robust and demonstrate durable efficacy with a very low complication rate, particularly in experienced hands. Various techniques for sling placement and different meshes are employed according to physician preference, but all appear to be equally effective.
- SUI remains a common and distressing condition that adversely affects quality of life.
- There are no approved pharmacologic agents for SUI.

The FDA has looked at the issue of safety and efficacy related to midurethral slings and found the following in a 2013 statement on considerations about surgical mesh for SUI that:

- The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year.
- The use of mesh slings in transvaginal SUI repair introduces a risk not present in traditional non-mesh surgery for SUI repair, which is mesh erosion, also known as extrusion.
- Erosion of mesh slings through the vagina is the most commonly reported mesh-specific complication from SUI surgeries with mesh. The average reported rate of mesh erosion at one year following SUI surgery with mesh is approximately 2 percent. Mesh erosion is sometimes treated successfully with vaginal cream or an office procedure where the exposed piece of mesh is cut. In some cases of mesh erosion, it may be necessary to return to the operating room to remove part or all of the mesh.

## **XI. Conclusion:**

In conclusion, the TVT has revolutionized health care for women by providing a less invasive, durable, quicker, and safer treatment option for women seeking surgical

treatment for stress urinary incontinence. TVT quickly became the gold standard after withstanding the scrutiny of level 1 RCTs, which have repeatedly duplicated the early TVT results of high cure rates and low complications. Because TVT is the best-studied device and procedure to treat SUI, surgeons are confidently able to recommend TVT as the first-line surgical treatment for SUI.

Signed September 15, 2015

Handwritten signature of Kimberly Kenton in black ink.

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Kimberly Kenton, M.D., MS

# Exhibit A



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**Kimberly Kenton, MD, MS, FACS, FACOG**

Professor

Division Chief, Female Pelvic Medicine & Reconstructive Surgery  
Fellowship Director, Female Pelvic Medicine & Reconstructive Surgery  
Medical Director, Women's Integrated Pelvic Health Program  
Departments of Obstetrics & Gynecology and Urology  
Division of Female Pelvic Medicine & Reconstructive Surgery  
Northwestern University Feinberg School of Medicine  
Prentice Women's Hospital  
250 E. Superior, Suite 05-2365  
Chicago, IL 60611  
[REDACTED]

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**Education:**

M.S.	Clinical Research Design & Statistical Analysis University Of Michigan, Ann Arbor, MI	2003-05
Fellowship	Female Pelvic Medicine & Reconstructive Surgery Loyola University Medical Center, Maywood, IL	2000-02
	Rush University Medical Center, Chicago, IL	1999-00
Residency	Obstetrics & Gynecology Rush University Medical Center, Chicago, IL	1995-99
M.D.	Rush Medical College/Rush University, Chicago, IL	1991-95
Fellowship	Graduate Research, Biology	1988-91
B.S.	Biology University of Illinois, Urbana-Champaign, IL	1984-88

**Academic Appointments:**

Professor Chief, Female Pelvic Medicine & Reconstructive Surgery Department of Obstetrics & Gynecology and Urology Northwestern University Feinberg School of Medicine Chicago, IL	2013-
Fellowship Director, Female Pelvic Medicine & Reconstructive Surgery Department of Obstetrics & Gynecology and Urology Northwestern University Feinberg School of Medicine Chicago, IL	2013-
Professor Departments of Obstetrics & Gynecology and Urology Loyola University Stritch School of Medicine Maywood, IL	2012-
Associate Professor Tenure Director, Division of Female Pelvic Medicine & Reconstructive Surgery Departments of Obstetrics & Gynecology and Urology Loyola University Stritch School of Medicine Maywood, IL	2007- 2011- 2011 -
Fellowship Director, Female Pelvic Medicine & Reconstructive Surgery Departments of Obstetrics & Gynecology and Urology Loyola University Stritch School of Medicine Maywood, IL	2007-
Residency Program Director Associate Residency Director Department of Obstetrics & Gynecology	2010- 2003-10

Loyola University Stritch School of Medicine  
Maywood, IL

Assistant Professor 2003-07  
Departments of Obstetrics & Gynecology and Urology  
Loyola University Stritch School of Medicine  
Maywood, IL

Instructor 2002  
Departments of Obstetrics & Gynecology and Urology  
Loyola University Stritch School of Medicine  
Maywood, IL

Instructor 1999  
Department of Obstetrics & Gynecology  
Rush University/Rush Medical College  
Chicago, IL

**Licensure and Certification:**

Diplomate, American Board of Obstetrics and Gynecology 2003  
License: Physician and Surgeon, Illinois 1995  
License: Controlled substance, Illinois 1999

**Professional Memberships & Activities:**

American Board of Obstetrics & Gynecology, Diplomate 2003-  

- Female Pelvic Medicine & Reconstructive Surgery Division Member 2009-
- Oral Board Examiner 2008-
- Written Exam Committee, FPMRS 2012-

Accreditation Council for Graduate Medical Education  
Obstetrics & Gynecology Residency Review Committee 2012-

National Board of Medical Examiners/United States Medical Licensing Exam  

- CCSC Scoring Committee 2012-

American College of Obstetricians & Gynecologists, Fellow 2003-  

- Prolog - Female Pelvic Medicine & Reconstructive Surgery, Chair 2014
- Clinical Document Review Panel-Gynecology 2012-
- Gynecology Practice Bulletin Committee 2010-12
- Junior Fellow 1995-03
- District IV, Junior Fellow Chair 2000
- District IV, Junior Fellow Vice-Chair 1999
- ACOG Junior Fellow Representative to Council of Medical Specialty Societies 1999-01
- Illinois Section, Junior Fellow Chair 1997
- Illinois Section, Junior Fellow Vice-Chair 1996

American Urogynecologic Society 1996-  

- Board of Directors 2007-13
- AUGS Foundation Board of Directors 2011-

• Grant Review Committee	2007-
• Education Committee - Chair	2007-10
• Education Committee	2001-05
• Fellow Representative	1999-02
Society of Gynecologic Surgeons	2005-
• Liason to LCOG/SCOG	2012-
• Executive Committee	2010-
• Education Committee Chair	2010-12
• Executive Board	2010-
• Research Committee	2006-2009
• Systematic Review Group	2008-9
• Fellow's Pelvic Research Network Steering Committee	2008-10
American College of Surgeons, Fellow	2005-
Society of Urodynamics & Female Urology	2006-
International Urogynecologic Society	2005-
• Research & Development Committee	2005-10
International Continence Society	2005-
American Professors of Obstetrics & Gynecology	2004-
American Association of Neuromuscular & Electrodiagnostic Medicine	1999-
• Course Committee	2004-06
American Medical Society	1992-03
Illinois State Medical Society	1992-03
Chicago Gynecologic Society	2005-
Chicago Urogynecologic Society	2003-
<b>Editorial Boards:</b>	
Female Pelvic Medicine & Reconstructive Surgery	Reviewer 2010-
	Section Editor 2011-
Obstetrics & Gynecology	Reviewer 2000-
	Editorial Board 2013
	Editorial Intern 1999
	Top 10% Reviewers 2003, 2012
British Journal of Obstetrics & Gynecology	Reviewer 2014-
New England Journal of Medicine	Reviewer 2007-
Up to Date	Reviewer 2006-
Neurourology & Urodynamics	Reviewer 2006-
Health Policy	Reviewer 2005-
J Reproductive Medicine	Reviewer 2005-
J of Urology	Reviewer 2004-
International J Obstetrics & Gynecology	Reviewer 2002-

American J Obstetrics & Gynecology	Reviewer	2001-
• Top 5% Reviewers		2004
International Urogynecology Journal	Reviewer	2001-

**Awards and Honors:**

CREOG Faculty Award for Excellence in Resident Education	2015
Friends of Prentice Distinguished Physician Award	2014
Outstanding Teacher Award Feinberg School of Medicine	2014
Chicago Top Doctors	2013
ACOG Mentor Award	2011, 2012
Society for Women's Health Research Award for Scientific Contributions to Women's Health	2009
AAMC Mid-Career Faculty Development Seminar	2007
CREOG Faculty Award for Excellence in Resident Education	2007
APGO/Solvay Educational Scholars Program	2005
Berlex Foundation Junior Faculty Development Award	2002
ACOG "Stump the Professor" Award	2002
Sigma Xi Society Outstanding Scientific Project Award	1999,98,96
Resident Surgical Skills Award	1999
Rush Surgical Society Resident Research Award	1998
Department of Ob-Gyn Resident Research Day Award	1998
Berlex Resident Teaching Award	1997
Outstanding Ob-Gyn Student Award	1995
Forest Hospital Foundation Fellowship	1993,94
Rush Medical College Dean's Summer Research Fellowship	1992
De Paul University Teaching Fellowship	1999-91

**Committee Assignments & Administrative Service:****Loyola University Stritch School of Medicine**

Faculty Development Review Committee	2011-
Graduate Medical Education Committee	2009-
• Chair Grievance Committee	2011, 12
Faculty Senate	
• President	2009-2011
• President Elect	2007-08
• Vice President	2004-06
Research Funding Committee	2006-
Faculty Incentive Steering Committee	2008
Liason Committee on LCME	2007-08
Education for MD Degree (LCME)	2007-08
Medical Council	2004-06
EPIC Medical Records Subcommittee	2004-06
EPIC Template Committee	2004-06
Department of Obstetrics & Gynecology, Education Committee	2002-

**Rush University/Rush Medical College**

Committee on Committees	1992-95
Student Judicial Review	1991-95

**Grants:****Current Research Support**

1U01DK097776-01

Cella (PI)

5/13-

Kimberly Kenton, MD, MS

## Symptoms of Lower Urinary Tract Dysfunction Research Network

Cooperative research network to develop quality symptom based instruments and better define phenotypes of patients with lower urinary tract dysfunction.

Role: Co-investigator

**Completed Research Support**

1U10 DK60379-01 Brubaker (PI) 07/10-06/13

The Urinary Incontinence Treatment Network

This is a multicenter network established to carry out clinical trial in women with urinary incontinence.

Role: Co-PI

5U10 HD041250 Brubaker (PI) 08/11-07/14

The Pelvic Floor Disorders Network

This is a multicenter network established to investigate pelvic floor disorders in women.

Role: Co-Investigator

RC1 EB010649-01 Kenton (PI) 09/09-08/11

Comparative Effectiveness of Robotic vs Open Sacrocolpopexy for Vault Prolapse

This is a randomized comparative effectiveness trial comparing two routes of access for surgical treatment of pelvic organ prolapse.

Role: PI

1U10 DK60379-01 Brubaker (PI) 09/01-06/10

The Urinary Incontinence Treatment Network

This is a multicenter network established to carry out clinical trial in women with urinary incontinence.

Role: Co-PI

5U10 HD041250 Brubaker (PI) 09/01-06/11

The Pelvic Floor Disorders Network

This is a multicenter network established to investigate pelvic floor disorders in women.

Role: Co-Investigator

K23 HD047325-01A1 Kenton (PI) 09/04-08/10

Role or Urethral Neuromuscular Function

This goal of this study is to characterize urethral neuromuscular function in stress incontinent and continent women using neurophysiologic and urodynamic testing.

Role: PI

NIH/NIDDK – 1U10 DK60379-01 Brubaker (PI) 09/01-06/06

Urinary Incontinence Treatment Network

Role: Co-PI

Contribution to the Project: Responsible for project development, recruitment, data collection, and publication

NIH/NICHD 5U10 HD04 1250 Brubaker (PI) 09/01-09/06

Pelvic Floor Disorders Network

Role: Co-investigator

Contribution to the Project: Responsible for project development, recruitment, data collection, and publication.

Pfizer Detrol Competitive Grant	Kenton (PI)	07/07-12/10
Neuromuscular Function in the Urethra of Women with Overactive Bladder		
The goal of this study is to characterize urethral neuromuscular function in women with overactive bladder.		

Pfizer Investigator Initiated Grant	Kenton (PI)	02/04-02/06
Effect of Tolterodine on Sensory Thresholds in the Lower Urinary Tract		
The aim of this study was to determine the affect of anticholinergic medication on urethral afferent nerve function.		

ACOG Award: Urogynecology of Post-reproductive Women      Kenton (PI)      07/99-06/00  
 Role of Electromyography in Predicting Outcome After Burch Colposuspension  
 This study investigated quantitative urethral EMG and outcomes of stress incontinence surgery.

## NIH activities

## Urinary Incontinence Treatment Network

- Steering Committee, Co-PI - 2008-
- Trial of Midurethral Slings (TOMUS) Protocol Committee 2005-
- E-TOMUS Protocol Committee 2008-
  - Chair
- Fitness Intervention Trial Protocol Committee 2008-
  - Chair
- Secondary Procedures for Incontinence Comparative Effectiveness (SPICE) Protocol Committee 2009-
  - Chair
- Publications Committee Chair 2009-2011

## Pelvic Floor Disorders Network Grant # 1U10 HD41250-01

- Publications Committee 2006-2008
- Outcomes Following Vaginal Prolapse Repair and Midurethral Sling Trial (OPUS) Protocol Committee 2006-
- ROSETTA Protocol Committee 2009-
- UI Prevention Protocol Committee 2009-
- Fitness Intervention Trial Protocol Committee 2009-
  - Chair

National Institutes of Child Health and Human Development, Basic Science and Translational Research in Female Pelvic Floor Disorders Conference, 2003

National Institute for Diabetes and Digestive and Kidney Diseases, State of the Science Conference: Prevention of Fecal and Urinary Incontinence in Adults. 2007

Scientific Review Panel, O'Brien Urology Center Grants. 2008

National Institute for Diabetes and Digestive and Kidney Diseases, New Research Directions for Urinary Incontinence Symposium, Planning Committee. 2009

Office of Research on Women's Health, Moving into the Future: New Dimensions & Strategies for Women's Health at the NIH: Chair, Bladder & Pelvic Floor Work Group. 2009

Scientific Review Panel, O'Brien Urology Center Grants. 2009



Scientific Review Panel, 05 ZHD1 DSR-L (08) 1 - Pelvic Floor Disorders. 2009

Scientific Review Panel, ZRG1 DKUS-G (12). 2009

Scientific Review Panel, ZRG1 DKUS-G (11)B. 2009

Scientific Review Panel, ZRG1 DKUS-G (51)S. 2009

Scientific Review Panel, 10 ZRG1 DKUS-G (80)S. 2009

Special Emphasis Panel/Scientific Review Group 2011/05 ZRG1 DKUS-G (11) B. 2011

- Chair

Scientific Review Panel, 10 ZRG1 DKUS-G (12)S. 2011

Special Emphasis Panel, Symptoms of Lower Urinary Tract Dysfunction Network, ZDK1- GRB-6 (02) 2012

Special Emphasis Panel/Scientific Review Group ZRG1 DKUS-L (80). 2012

Special Emphasis Panel/Scientific Review Group ZRG1 DKUS-L (80). 2015

## **Educational Activities**

### ***Local Contributions***

#### **Medical school course**

Loyola University Stritch School of Medicine

2007-12

STAR Program

I mentor a 1<sup>st</sup> year medical student each summer on an independent researcher project funded through the Dean's office. Students (N-6) have all published and presented their work locally and/or nationally.

In addition, I have given the following lectures as part of the formal STAR didactic series.

2007-8: Research in Clinical Practice

2009: Study Design

2010-12: Basics of Analyzing Research Data

Loyola University Stritch School of Medicine

2002-12

Introduction to the Practice of Medicine – 1

I mentored a first year medical student for the year. They attended my clinics and surgeries when available and had the opportunity to take a complete history and physical exam with special attention on the pelvic floor.

Loyola University Stritch School of Medicine

2003-13

Gross Anatomy: Pelvic Anatomy Laboratory

Attended laboratory sessions on pelvic anatomy (typically 2 per year) and reviewed clinically relevant pelvic and reproductive anatomy with the students.

Rush Medical College

1998-99

Gross Anatomy Course

Invited Lecturer: Clinical Correlation: Pelvic and Perineum

**Local invited teaching presentations**

What's New In Pelvic Floor Disorders Grand Rounds: St Elizabeth's Hospital	2014
What's New In Pelvic Floor Disorders Grand Rounds: St Mary's Hospital	2014
What's New In Pelvic Floor Disorders Grand Rounds: West Suburban Hospital	2014
Recent Advances in Pelvic Floor Disorders Moraine Valley Community College	2013
Recent Advances in Pelvic Floor Disorders Women's Health Research Institute Northwestern University Feinberg School of Medicine	2013
Selecting the Best Operation for Pelvic Organ Prolapse Grand Rounds: Department of Obstetrics & Gynecology Northwestern University	2013
Neurophysiology of the Pelvic Floor Grand Rounds: Loyola Department of Neurology	2006
Invited Lecturer Advances in Urogynecology Society of Urologic Nurses Association	2006
Neurophysiology of the Pelvic Floor Grand Rounds: Schwab Rehabilitation Institute, Chicago, IL	2005
2 lectures: Evaluation of Pelvic organ prolapse & Surgical Anatomy 26 <sup>th</sup> Annual Obstetrics and Gynecology Review Course	2005
Vaginal Agenesis and Reconstruction Grand Rounds: Loyola Department of Ob/Gyn, Chicago, IL	2004
Vaginal Reconstruction Grand Rounds: Loyola Department of Plastic Surgery, Chicago, IL	2004
Standardization of Terminology of Lower Urinary Tract Function Grand Rounds: Loyola Department of Urology, Chicago, IL	2003
Neural Injuries in Pelvic Surgery Grand Rounds: Loyola Department of Ob/Gyn, Chicago, IL	2000
What Every Pelvic Surgeon Needs to Know About the Nervous System Grand Rounds: Rush Department of Ob/Gyn, Chicago, IL	1999
Neural Injuries in Obstetrics and Gynecology Grand Rounds: Rush Department of Ob/Gyn, Chicago, IL	1998

Continuing medical education course

Updates in Women's Health Care 2005  
 Advances in Female Pelvic Medicine and Reconstructive Surgery  
 Invited lecturer  
 1-hour lecture

Illinois ACOG: Updates in Urogynecology 2005  
 Burch Procedure. Is it alive and well?  
 1-hour lecture and 30 minute group panel

Advisory and supervisory responsibilities

Supervise and teach urogynecology fellows, Ob/Gyn and Urology residents, and 2002-12  
 medical students during my ambulatory clinics.

Mentor medical students and residents on clinical research projects. I have directly 2001-12  
 supervised numerous medical students, urology and Ob/Gyn residents.

Mentor fellows on designing, implementing, analyzing, and writing clinical research 2002-09  
 projects. I spend at least 4 hours per weeks outside of scheduled time working with  
 the fellows on their research projects.

Responsible for ensuring the Female Pelvic Medicine and Reconstructive Surgery 2002-09  
 fellows are competent in urodynamic testing. I meet with them outside of clinic and  
 conference to review equipment, trouble shooting, and clinical scenarios. I am in the  
 process of formalizing this teaching endeavor to an objective structured assessment  
 of technical skills (OSATS) exam, which can be validated and published for use in  
 other programs.

Teaching leadership

Residency Director, Obstetrics & Gynecology 2010-

Fellowship Director, Female Pelvic Medicine & Reconstructive Surgery 2007-

Fellowship Graduates:

1. Lior Lowenstein, MD, MS	Associate Professor, Ramban Medical Center Haifa, Israel
2. Thythy Pham, MD	Private Practice, Resurrection Hospital, Chicago, IL
3. Shameem Abbasy, MD, MPH	Assistant Professor, Rush University
4. Megan Tarr, MD, MS	Assistant Professor, Carolinas Medical Center
5. Jackie Cunkelman, MD, MPH	Private Practice, Denver, CO
6. Olga Ramm, MD, MS	Kaiser Permanente, Oakland, CA
7. Cynthia Fok, MD, MPH	Assistant Professor, University of Minnesota
8. Melinda Abernethy MD, MPH	Assistant Professor, Johns Hopkins University
9. Margaret Mueller MD	Assistant Professor, Northwestern University

Associate Residency Program Director, Gynecology & Research 2003-10

1<sup>st</sup> Female Pelvic Medicine & Reconstructive Surgery Fellowship Directors Meeting 2008

With the support of the American Board of Obstetrics & Gynecology, I brought together  
 national leaders in Obstetrics & Gynecology and Urology to plan and implement a 1-day meeting  
 of all Board-approved Female Pelvic Medicine & Reconstructive Surgery Fellowship Directors.

Clinical Research Education Study Teams (CREST) 2006 -  
Co-Course Director

We are developing a novel approach to resident research education. Each new residency class meets monthly with a dedicated faculty member to design and implement a research project. The residents are then able to work as a network to collect, analyze and present data. We believe this will raise the quality of resident research from retrospective chart reviews to prospective clinical trials, facilitate recruitment since the residents are aligned in their mission, and make the process more enjoyable. In addition, we are developing a formal research curriculum based on a survey of US Ob/Gyn residency program directors, including how to design a research project, write a research protocol, prepare an IRB submission, analyze and interpret results, prepare an abstract, write a manuscript, and interpret the published literature.

I have been working with the Ob/Gyn residents who just completed their first year of residency. They have all passed their human subjects exam and developed a prospective research protocol to investigate patient's knowledge and expectations before delivery to their satisfaction after delivery, which will be ready for IRB submission next month.

Course Director: Clinical Anatomy and Surgical Skills Training (CASST) 2005-07

I developed multidisciplinary, multicenter clinical anatomy and surgical skills curriculum for junior residents in Ob/Gyn and Urology. I assembled faculty and residents from 2 other Chicago area Ob/Gyn programs and our Urology department. The program consisted of 5, 4-hour sessions, which included short didactics, surgical skills laboratories, and anatomy reviews on prosected cadavers. A description of the curriculum has been presented at 5 national meetings (educational and gynecologic surgery). Two peer reviewed publications have resulted from the program. In addition, It won the *Presidential Prize Paper for Research in Gynecologic Surgery* at the Society of Gynecologic Surgeon's annual meeting in 2007. Mayo Clinic in Rochester Minnesota has adopted and implemented the CASST curriculum for their Ob/Gyn residents using our materials.

Fellow's Pelvic Research Network 2007-08

I facilitated one of our fellows in developing and finding national sponsorship from the Society of Gynecologic Surgeons for a multicenter, research network for fellows in Female Pelvic Medicine and Reconstructive Surgery. I am on the advisory board, which teaches and mentors fellows from 20 different fellowship programs to design, implement, analyze, write, and publish multicenter research projects.

Leischner Institute Scholars Program 2007-08

I developed a faculty development program, which was sponsored by the Dean's office designed to mentor junior faculty from clinical departments in educational techniques and educational research. Two faculty from six departments were nominated by their chairperson to participate in the 18 month long program. In addition to monthly evening didactics, each faculty was expected to implement and write-up a scholarly project for publication. I coordinated the program with our Dean of Faculty Development and served as a faculty mentor.

Course Director: Orientation 2006

I coordinated a one-day, multicenter intern orientation for Ob/Gyn residents from Loyola, Rush, and Illinois Masonic Medical Centers. The program was held in Stritch School of Medicine and included short didactic and hands-on surgical skills and obstetric training sessions. I coordinated faculty from all three institutions.

APGO Solvay Scholar 2006-07

I am currently accepted in a national program sponsored by the American Professors of Gynecology and Obstetrics designed to train leaders in medical student and resident education about curricular design and educational research. The program lasts 18 months and includes 5 2-5 day sessions with national leaders in medical and surgical education. All scholars are required to do an educational or curricular development project, which will be presented at the 2007 annual scientific meeting. I am developing a curriculum designed to teach residents about clinical research and study design. The needs assessment is completed. I am in the curricular design phase.

#### Urogynecology Fellow Conference

2005-

Wednesday mornings are devoted to divisional academic conferences for our fellows. I have coordinated the academic conferences for the last 2 years. Conference include: 'uroconference' – this conference includes a systematic review national fellowship objectives, a unit on biomedical writing, invited speakers doing related basic science or clinical research, a unit of neurophysiology and electrodiagnostic testing; 'case conference' where faculty, fellows, and residents review urodynamics and surgical cases for the next week; 'journal club'; and 'research conference' - research conference varies by week to include presentation of new concepts, study design and biomedical writing, database analysis, and brainstorming sessions.

#### Intern Orientation

2004-06

I developed a 2-day orientation program for the first year Ob/Gyn residents, which included didactics, problem based learning, an introduction to the operating room and a surgical skills session.

#### Resident Mock Oral Board Exam

2004-06

I restructured the annual oral exam for 2<sup>nd</sup> year Ob/Gyn residents. The exam now mimics the format, including standardized cases and a surgical case log, of the Ob/Gyn oral boards.

#### Summer Lecture Series

2004-05

I developed a weekly summer conference series for the first and second year Ob/Gyn residents to cover important clinical topics in gynecology and obstetrics.

#### Morning Gynecology Rounds

2003-06

I implemented daily gynecology rounds with the residents and medical students on various gynecology services. A member of the Female Pelvic Medicine and Reconstructive Surgery faculty meets with the residents daily at 6:30 am to discuss management of complicated cases.

#### Names of advisees/trainees:

<u>Training Duration</u>	<u>Role</u>	<u>Name</u>	<u>Current Position</u>
3 years	Fellow, FPMRS	Eman Elkadry	Instructor, Harvard
3 years	Fellow, FPMRS	Fareesa Kahn	Asst Professor, Washington University
3 years	Fellow, FPMRS	Tina Mahajan	Asst Professor, Case Western Reserve
3 years	Fellow, FPMRS	Beth Mueller	Associate Professor, Loyola
3 years	Fellow, FPMRS	Megan Tarr	Assistant Professor, Cleveland Clinic
3 years	Fellow, FPMRS	Olga Ramm	Kaiser Oakland
3 years	Fellow, FPMRS	Jackie Cunkelman	Private Practice, Denver, CO
3 years	Fellow, FPMRS	Leslie Rickey	Assistant Professor, U of Maryland
3 years	Fellow, FPMRS	Lior Lowenstein	Assistant Professor, Haifa, Israel
7 years	Fellow, FPMRS	Thythy Pham	Private Practice, Resurrection
3 years	Fellow, FPMRS	Yashika Dooley	Major, US Air Force, San Antonio, TX
3 years	Fellow, FPMRS	Shameem Abbasy	Assistant Professor, Rush University

4 years	Resident, OG	Kristin Rooney	Attending, Rochester, New York
2 years	Medical Student	Cynthia Brincat	Assistant Professor, Loyola
3 years	Medical Student	Amelia Fitz	Family Medicine
3 years	Resident, OG	Carley Davis	Asst Professor, Medical College of WI
1 year	Medical Student	Joel Lopez	Internal Medicine
1 year	Medical Student	Adam May	Internal Medicine
1 year	Medical Student	Jessica Remke	Emergency Medicine
4 years	Resident, OG	Mindy Lukens	Instructor, Northwestern University
4 years	Resident, OG	Maryam Guiahi	Assistant Professor, U of CO
4 years	Resident, OG	Megan Trester	Private Practice, WI
4 years	Resident, OG	Stephanie Hearty	Faculty, IL Masonic Medical Center
4 years	Resident, OG	Charles Anderson	Fellow, Gyn-Oncology, U of CO
3 years	Resident, OG	Darby Murphy	Private Practice, Chicago
3 years	Resident, OG	Danielle Burkett	Private Practice, Dallas
3 years	Resident, OG	Joanna Horwitz	Private Practice, Chicago
3 years	Resident, OG	Vanessa Kennedy	Fellow, Gyn-Oncology
4 year	Resident, OG	Vance Broach	Fellow, Gyn-Oncology
4 year	Resident, OG	Lyndsey Day	Private Practice, Iowa
4 year	Resident, OG	Ben Barenberg	Fellow, FPMRS
2 years	Resident, Urology	Tony Polcari	Fellow, Endourology
5 years	Resident, UVA	Megan Schmidt	Obstetrics & Gynecology

**Regional Contributions**

Chicago, IL 2014

Grand Rounds: What's New in Pelvic Floor Disorders  
Norwegian American Hospital

Chicago, IL 2014

Grant Rounds: Recent Advances in Urinary Incontinence  
St Mary & Elizabeth's Hospital

Chicago, IL 2013

Grand Rounds: Recent Advances in Pelvic Floor Disorders  
West Suburban Hospital

Chicago, IL 2013

Invited Lecturer  
Northwestern University Women's Health Research Institute  
Recent Research Advances in Pelvic Floor Disorder

Chicago, IL 2012

Invited Lecturer  
Pelvic Floor Disorders  
American Urologic Association  
Postgraduate Course for Primary Care Physicians

Chicago, IL 2011

Invited Lecturer  
Participation in Clinical Research  
The Center for Information & Study on Clinical Research Participation  
Northwestern University

Chicago, IL Invited Lecturer Advances in Urinary Incontinence Treatment Society Of Urologic Nurses Association	2007
Indianapolis, IN Peer Reviewed Oral Presentation Clinical Anatomy and Surgical Skills Training Central Group on Education Affairs	2007
Chicago, IL Invited Lecturer Evaluation and Management of Urinary Incontinence in Women 59 <sup>th</sup> and 60 <sup>th</sup> Annual Midwest Clinical Conference	2003-04
Chicago, IL Invited Lecturer Evaluation and Management of Pelvic Floor Disorders Society of Urologic Nurses Association	2003
<b><i>National Contributions</i></b>	
Cincinnati, OH Fellow Surgical Course Invited Instructor Nerve Injuries in Pelvic Surgery; Midurethral sling American Urogynecologic Society	2015
New Orleans, LA American Urologic Association Postgraduate Course: Robotic Sacrocolpoxy	2015
Chapel Hill, NC University of North Carolina Department of Obstetrics & Gynecology Invited Speaker: Neurologic Complications of Obstetrics & Gynecology; Urology for the Urogynecologist	2015
Baltimore, MA Johns Hopkins Medical Center Department of Obstetrics & Gynecology Howard Kelly Lectureship in Reconstructive Pelvic Surgery What Every Gynecologist Needs to Know about Urology	2015
Roanoke, VA Julian H. Meyer Sr, MD Visiting Professorship Department of Obstetrics & Gynecology Research Day Selecting the Best Operation for Pelvic Organ Prolapse Virginia Tech Carillion Clinic	2015
Baltimore, MD American Urologic Association Summer Research Conference	2014



## Phenotyping Lower Urinary Tract Symptoms

Cincinnati, OH Fellow Surgical Course Invited Instructor Robotic Sacrocolpopexy; Nerve Injuries in Pelvic Surgery; Retropubic Anatomy International Academy of Pelvic Surgeons	2014
Washington, DC Invited Instructor: Minimally Invasive Sacrocolpopexy; Posterior Compartment Fellows Postgraduate Course: Anatomy American Urogynecologic Society/International Urogynecologic Association	2014
Scottsdale, AZ Postgraduate Course: Surgical Anatomy Society of Gynecologic Surgeons	2014
Cincinnati, OH Fellow Surgical Course Invited Instructor Robotic Sacrocolpopexy; Nerve Injuries in Pelvic Surgery; Retropubic Anatomy International Academy of Pelvic Surgeons	2013
Sunnyvale, CA Fellow Surgical Course: Robotics in Pelvic Reconstruction Society of Gynecologic Surgeons	2013
American Urogynecologic Association Leadership Program Invited Speaker: Board of Directors: Member at large	2013
San Diego, CA Postgraduate Course: Robotics for Reconstructive Pelvic Surgery Invited Speaker: Sacrocolpopexy American Urologic Association Annual Meeting	2013
Charleston, SC Postgraduate Course: Surgical Complications Nerve Injuries in Pelvic Surgery Society of Gynecologic Surgeons	2013
Sunnyvale, CA Fellow Surgical Course: Robotics in Pelvic Reconstruction Society of Gynecologic Surgeons	2012
Las Vegas, NV Armed Forces District ACOG Robert C. Cefalo Memorial Lecture How to Start a Resident Research Curriculum	2012

Long Island, NY Long Island Jewish Medical Center Department of Obstetrics & Gynecology Grand Rounds: Office Urogynecology for the Generalist	2012
Providence, RI Postgraduate Course: Urology for the Urogynecologist Invited Speaker: Top 10 Things I Learned from Urology American Urogynecologic Association Annual Meeting	2011
Albuquerque, New Mexico University New Mexico Department of Obstetrics & Gynecology Visiting Professor Getting Residents Excited About Research	2011
Sunnyvale, CA Fellow Surgical Course: Robotics in Pelvic Reconstruction Society of Gynecologic Surgeons	2011
Washington, DC Postgraduate Course: Robotics for Reconstructive Pelvic Surgery Invited Speaker: Sacrocolpopexy American Urologic Association Annual Meeting	2011
Charlottesville, VA University of Virginia Department of Obstetrics & Gynecology Visiting Professor and Lester A. Wilson Lecturer Selecting the Best Operation for Prolapse Repair	2010
St Petersburg, FL Invited Speaker: Outcomes Research in Pelvic Floor Disorders Society of Urodynamics & Female Urology Annual Meeting	2010
Hollywood, FL Postgraduate course: Essentials in Education Postgraduate Course: Curriculum Development, Effective Teaching, & Educational Scholarship Invited Speaker American Urogynecologic Society	2009
Chicago, IL World Robotic Gynecology Congress Invited speaker: Robotic Sacrocolpopexy after Supracervical Hysterectomy University of Michigan	2009
Las Vegas, Nevada Laparoscopy in Female Pelvic Medicine Invited Speaker: Robotic Sacrocolpopexy Society of Female Urology and Urodynamics Annual Meeting	2009
Orlando, Florida	2008

Postgraduate Course: Advanced Gynecologic Surgery

Invited Speaker

(1) Sacrocolpopexy: Routes of Access

(2) Taking Things Out: Mesh Complications

(3) Office Procedures for Urinary Incontinence

Society for Gynecologic Surgeons

Chicago, Illinois

2008

Postgraduate Course: Anatomy of the Pelvic Floor

Course Director: Invited speaker, organized, and planned a half day anatomy course.

American Urogynecologic Society Annual Meeting

Chicago, Illinois

2008

Postgraduate Course for Allied Health Professionals

Invited Speaker

Neurophysiologic Testing

American Urogynecologic Society Annual Meeting

Flint, Michigan

2008

Invited Speaker

Complications of Minimally Invasive Surgery

Genesis Health System

Jackson, Mississippi

2008

Mississippi Section ACOG

Invited Speaker

Complications of Mesh in Pelvic Surgery; Postoperative Voiding Dysfunction

University of Mississippi Ob-Gyn Alumni Association

Washington, DC

2007

Invited Speaker

Research Education

Department of Obstetrics & Gynecology

Georgetown & Washington Hospital Center

Dallas, TX

2007

Visiting Professor

Department of Obstetrics & Gynecology

University of Texas-Southwestern

Dallas, TX

2007

Invited Speaker

Neural Injuries in Pelvic Surgery

Department of Urology

University of Texas-Southwestern

Hollywood, FL

2007

Postgraduate Course: Educational Research Retreat

Facilitator and Invited Speaker: Getting Research Ready for Publication

American Urogynecologic Society Annual Scientific Meeting

Anaheim, CA

2007

Postgraduate Course: Reconstructive Surgery for the Advanced Surgeon

Invited Speaker

(1) Reconstructive Surgery for the Apex

(2) Patient Expectations, Goal Selection, Goal Achievement, & Satisfaction.

American Urologic Association Annual Scientific Meeting

Anaheim, CA

2007

Invited Speaker

Debate for POP-Q

Society of Urodynamics and Female Urology Meeting

Long Beach, CA

2007

Invited Speaker

Resident Education: Programs that Promote Faculty and Resident Scholarship

University of California-Irvine

Department of Obstetrics & Gynecology Grand Rounds

Orlando, FL

2007

*Course Director:* Complications in Pelvic Reconstructive Surgery

I planned and coordinated an interactive half day postgraduate course given before the annual meeting of the Society of Gynecologic Surgeons. I invited a multidisciplinary faculty, including urologists and gynecologists from around the country to participate in short didactics, case presentations, and panel discussions about complications and difficult surgical cases.

Cleveland, Ohio

2007

Invited Speaker

Resident Education Programs that Promote Scholarship

Case Western Reserve

Department of Obstetrics & Gynecology Grand Rounds

Birmingham, Alabama

2006

Invited Speaker

Is There a Role for Neurophysiologic Testing in Pelvic Floor Disorders?

University of Alabama

Phoenix, Arizona

2007

Washington, D.C.

2006

Monterey, California

2005

Atlanta, Georgia

2004

*Course Director:* Pelvic Floor Neurophysiology

American Association of Neuromuscular and Electrodiagnostic Medicine

I planned and coordinated this 4-hour didactic and hands on workshop. I assembled physiatry and urogynecology faculty from around the country, gave a 1-hour didactic, then taught four, 45 minute workshops on pelvic nerve conduction studies using volunteer subjects. Additionally, I wrote a monograph on Pelvic Floor Neurophysiology to distribute to participants.

Albuquerque, New Mexico

2006

Course: Treating Urinary Incontinence and Pelvic Organ Prolapse:

## A Hands-on Course in Pessary Fitting and Physical Therapy

## Invited Speaker

- (1) Using Physical Therapy and Pessaries to Treat Pelvic Floor Disorders;  
 (2) Can We Cure Pelvic Floor Disorders Non-surgically?

Tucson, Arizona 2006

Member of planning committee and small group facilitator

Educational Research Retreat

Society of Gynecologic Surgeons

Phoenix, Arizona 2006

Invited speaker

Urinary Incontinence: Step-by-Step Approach

Phoenix Gynecologic Society

Grand Bahamas, Bahamas 2006

Plenary presentation

Current Perception Threshold Testing

Society of Female Urology and Urodynamics Annual Meeting

Atlanta, Georgia 2005

San Diego, California 2004

Postgraduate Course: Teaching and Evaluating Surgical Skills

Invited speaker: Teaching in the Operating Room

American Urogynecologic Society

Salt Lake City, Utah 2004

Postgraduate Course: Teaching the Teachers

Invited lecturer: Teaching and Evaluating Learner in the Operating Room

American Professors of Gynecology and Obstetrics Annual Meeting

San Francisco, California 2002

Toronto, Canada 2001

Albuquerque, New Mexico 2000

Vancouver, British Colombia 1999

Postgraduate Course: Pelvic Floor Neurophysiology

Workshop Instructor: Pudendal and Perineal Nerve Conduction Studies

American Association of Electrodiagnostic Medicine

**International Contributions**

Nice, France 2015

Postgraduate Courses: (1) Fellow's Course; (2) Complications in Pelvic Floor Surgery;  
 (3) Surgery for Pelvic Organ Prolapse

Invited lecturer

International Urogynecologic Society

Rio de Janeiro, Brazil 2014

Postgraduate Course:

Invited lecturer: (1) Tips & Tricks Laparoscopic Sacrocolpopexy (2) Selecting the Best  
 Operation for Prolapse (3) Pelvic Floor Anatomy

International Continence Society

Barcelona, Spain Postgraduate Course: Invited lecturer: (1) Surgical Anatomy for Reconstructive Surgery (2) Laparoscopy in RPS. International Continence Society	2012
Glasgow, Scotland Postgraduate Course: Invited lecturer: (1) Surgery for Apical Prolapse (2) Robotics in RPS. International Urogynecologic Society & International Continence Society	2011
Haifa, Israel Robotic surgery proctor Ramban Medical Center	2011
Toronto, Canada Postgraduate Course: Invited lecturer: (1) Robotic Approaches to Pelvic Reconstruction; (2) Assessment of Surgical Outcomes International Urogynecologic Society & International Continence Society	2010
San Francisco, CA Postgraduate Course: Invited lecturer: (1) Robotic Approaches to Pelvic Reconstruction; (2) Assessment of Surgical Outcomes International Continence Society	2009
San Francisco, CA Plenary Session Invited lecturer: Top 5 Reasons to NOT use Vaginal Mesh in Reconstructive Surgery International Continence Society	2009
Lake Como, Italy Postgraduate Course: Laparoscopic Prolapse Surgery Invited lecturer: Robotic Sacrocolpopexy International Urogynecologic Association	2009
Cairo, Egypt Postgraduate Course: Use of Mesh in Reconstructive Pelvic Surgery Invited lecturer: Concomitant Procedures & Complications during Sacrocolpopexy International Continence Society	2008
Barcelona, Spain Postgraduate Course: Training and Education in Endoscopy Invited lecturer: Setting Up a Multicenter Clinical Anatomy and Surgical Skills Training Program European Society of Human Reproduction and Embryology	2008
Guadalajara, Mexico Invited lecturer: Pelvic Floor Neurophysiology; Neural Injuries in Pelvic Surgery International Congress of Electrophysiology and Diagnostic Medicine	2008

**Publications (peer reviewed):**

1. Catanzarite T, Bernardi LA, Confino E, **Kenton K**. Ureteral trauma during transvaginal ultrasound-guided oocyte retrieval. *Female Pelvic Med Reconstr Surg*. 2015 Sep-Oct;21(5):e44-5.
2. Lewicky-Gaupp C, Leader-Cramer A, Johnson LL, **Kenton K**, Gossett DR. Wound complications after obstetric anal sphincter injuries. *Obstet Gynecol* 2015. May;125(5):1088-93. PMID 25932836
3. Tenfelde S, Tell D, Thomas TN, **Kenton K**. Quality of life in women who use pessaries for longer than 12 months. *Female Pelvic Med Reconstr Surg* 2015. May-Jun;21(3):146-9. PMID 25521465
4. Tarr ME, Brancato SJ, Cunkelman JA, Polcari A, Nutter B, **Kenton K**. Comparison of postural ergonomics between laparoscopic and robotic sacrocolpopexy: a pilot study. *J Minim Invasive Gynecol*. 2015 Feb;22(2):234-8. PMID 25315401.
5. Mueller MG, Ellimootil C, Abernethy MG, Mueller ER, Hohmann S, Kenton K. Colpocleisis: a safe, minimally invasive option for pelvic organ prolapse. *Female Pelvic Med Reconstr Surg*. 2015 Jan-Feb;21(1):30-3. PMID: 25185616
6. Summer S, Petzel A, Anderson J, **Kenton K**. Cervical cancer screening rates in a chart review of adolescent patients at an academic institution before and after the publication of the 2009 American Congress of Obstetricians and Gynecologists' recommendations. *Journal Pediatr Adolesc Gynecol*. 2015 Aug;28(4):258-62. PMID: 26026218
7. Greer WJ, Gleason JL, **Kenton K**, Szychowski JM, Goode PS, Richter HE. Medication Effects on Periurethral Sensation and Urethral Sphincter Activity. *Female Pelvic Med Reconstr Surg*. 2015 Mar-Apr;21(2):77-82. PMID: 25185603
8. **Kenton K**, Stoddard AM, Zyczynski H, Albo M, Rickey L, Norton P, Wai C, Kraus SR, Sirls LT, Kusek JW, Litman HJ, Chang RP, Richter HE; Urinary Incontinence Treatment Network. 5-Year Longitudinal Follow-up after Retropubic and Transobturator Midurethral Slings. *J Urol*. 2015 Jan193(1):203-10. PMID: 25158274
9. Mueller MG, Pilecki MA, Catanzarite T, Jain U, Kim JY, **Kenton K**. Venous thromboembolism in reconstructive pelvic surgery. *Am J Obstet Gynecol*. 2014 Nov;211(5):552.e1-6. PMID: 25068557
10. Abernethy MG, Davis C, Lowenstein L, Mueller ER, Brubaker L, **Kenton K**. Urethral sensation following reconstructive pelvic surgery. *Int Urogynecol J*. 2014 Nov;25(11):1569-73. PMID: 24825353
11. Catanzarite T, Rambachan A, Mueller MG, Pilecki MA, Kim JY, **Kenton K**. Risk factors for 30-day perioperative complications after the fort colpocleisis. *J Urol*. 2014 Sep;192(3):788-92. PMID: 24641911
12. Tarr ME, Rivard C, Petzel AE, Summers S, Mueller ER, Rickey LM, Denman MA, Harders R, Durazo-Arvizu R, **Kenton K**. Robotic objective structured assessment of technical skills: a randomized multicenter dry laboratory training pilot study. *Female Pelvic Med Reconstr Surg*. 2014 Jul-Aug;20(4):228-26. PMID 24978090
13. Amundsen CL, Richter HE, Menefee S, Vasavada S, Rahn DD, **Kenton K**, Harvie HS, Wallace D, Meikle S. The refractory overactive bladder: sacral neuromodulation vs. botulinum toxin assessment: ROSETTA trial. *Contemp Clin Trials*. 2014 Mar;37(2):272-83. PMID: 24486637
14. Anger JT, Mueller ER, Tarnay C, Smith B, Stroupe K, Rosenman A, Brubaker L, Bresee C, **Kenton K**. Robotic compared with laparoscopic sacrocolpopexy: a randomized controlled trial. *Obstet Gynecol*. 2014 Jan;123(1):5-12. PMID: 24463657



15. Guiahi M, Westhoff CL, Summers S, **Kenton K**. Training at a faith-based institution matters for obstetrics and gynecology residents: results from a regional survey. *J Grad Med Educ*. 2013 Jun;5(2):244-51. PMID: 24404267
16. Broach V, Day L, Barenberg B, Huang S, **Kenton K**, White P. Use of electronic health record-based tools to improve appropriate use of the human papillomavirus test in adult women. *J Low Genit tract Dis*. 2014 Jan;18(1):26-30. PMID: 23959396
17. McFadden BL, Constantine ML, Hammil SL, Tarr ME, Abed HT, **Kenton KS**, Sung VW, Rogers RG. Patient recall 6 weeks after surgical consent for midurethral sling using mesh. *Int Urogynecol J* 2013 Dec;24(12):2099-104. PMID: 23818127
18. Graziano S, Darby M, Braginsky L, Horwitz J, Kennedy V, Burkett D, **Kenton K**. Assessment of bowel function in the peripartum period. *Archives of Obstet Gynecol*. 2014 Jan;289(1):23-7. PMID: 23764932
19. Zimmern P, Litman H, Nager C, Sirls L, Krauss S, **Kenton K**, Wilson T, Sutkin G, Siddiqui N, Vasavada S, Norton P; for the Urinary Incontinence Treatment Network. Pre-operative urodynamics in women with stress urinary incontinence increases physician confidence, but does not improve outcomes. *Neurourol Urodyn*. 2014 Mar;33(3):302-6. PMID: 23553613
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21. Borello-France D, Burgio KL, Goode PS, Ye W, Weidner AC, Lukacz ES, Jelovsek JE, Bradley CS, Schaffer J, Hsu Y, **Kenton K**, Spino C; for the Pelvic Floor Disorders Network. Adherence to behavioral interventions for stress incontinence: rates, barriers, and predictors. *Phys Ther*. 2013 Jun;93(6):757-73. PMID: 23431210
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23. White P, **Kenton K**. Use of electronic medical record based tools to improve compliance with cervical cancer screening guidelines: effect of an educational intervention on physician's practice patterns. *J Low Genit Tract Dis*. 2013 Apr;17(2):175-8. PMID 23343700
24. Nager CW, Brubaker L, Litman HJ, Zyczynski HM, Varner RE, Amundsen C, Sirls LT, Norton PA, Arisco AM, Chai TC, Zimmern P, Barber MD, Dandreo KJ, Menefee SA, **Kenton K**, Lowder J, Richter HE, Khandwala S, Nygaard I, Kraus SR, Johnson HW, Lemack GE, Mihova M, Albo ME, Mueller E, Sutkin G, Wilson TS, Hsu Y, Rozanski TA, Rickey LM, Rahn D, Tennstedt S, Kusek JW, Gormley EA; the Urinary Incontinence Treatment Network. A randomized trial of urodynamic testing before stress-incontinence surgery. *N Engl J Med*. 2012 June 21;366(25):2358-67. PMID: 22551104
25. Wei JT, Nygaard I, Richter HE, Nager CW, **Kenton K**, Amundsen CL, Schaffer J, Meikle SF, Spino C; Pelvic Floor Disorders Network. A midurethral sling to reduce incontinence after vaginal prolapse repair. *N Engl J Med* 2012 Jun 21;366(25):2358-67. PMID 22716974
26. Gleason JL, **Kenton K**, Greer WJ, Ramm O, Szychowski JM, Wilson T, Richter HE. Sacral neuromodulation effects on periurethral sensation and urethral sphincter activity. *Neurourol Urodyn*. 2013 Jun;32(5):476-9. PMID: 23168535

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36. Mueller ER, **Kenton K**, Tarnay C, Brubaker L, Rosenman A, Smith B, Stroupe K, Bresse C, Pantuk A, Schulam P, Anger JT. Abdominal colpopexy: comparison of edoscopic surgical strategies (ACCESS). *Contemp Clin Trials.* 2012 Sep;33(5):1011-8. PMID: 22643040
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39. Tarr M, Klenov V, Tanzy M, Rivard C, McElhinney M, Brubaker L, Mueller E, FitzGerald M, **Kenton K**. Peri-operative bowel habits of women undergoing gynecologic surgery. *Female Pelvic Med Reconstr Surg*

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#### Non-print Materials

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10. **Kenton K**, Lowenstein L, Brubaker L. Tolterodine causes measurable restoration of urethral sensation in women with urge urinary incontinence. *J Pelvic Surgery* 2008;14(4):245.
11. **Kenton K**, Spirka T, Butler R, Damaser M, Brubaker L. Does aging affect sphincter function differently in continent versus stress incontinent women? *J Pelvic Surgery* 2008;14(4):296.
12. Lowenstein L, Pham T, Abbasy S, **Kenton K**, Brubaker L, Mueller E, Vardi Y, Gruenwald I, FitzGerald MP. Continuous measure of lower urinary tract sensation during bladder filling in women with detrusor overactivity. *J Pelvic Surgery* 2008;14(4):322-3.
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14. Khan F, Cunkelman J, Lowenstein L, **Kenton K**. Bowel symptoms: the under-reported urogynecologic complaint. *J Pelvic Surgery* 2008;14(4):337.
15. Lowenstein L, FitzGerald MP, **Kenton K**, Hatchet L, Durazo-Arvizu R, Goldman K, Brubaker L. Evaluation of urgency with a validated urgency severity and impact questionnaire: USIQ. *J Pelvic Surgery* 2008;14(4):322.
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17. Lowenstein L, **Kenton K**, Mueller ER, Brubaker M, Senka J, FitzGerald MP. Patients with painful bladder syndrome have altered response to thermal stimuli and catastrophic reaction to painful experience. *J Pelvic Surgery* 2008;14(4):301.
18. Lowenstein L, Hatchett L, **Kenton K**, Brubaker L, Durazo-Arvizu R, Goldman K, Mueller ER, FitzGerald MP. Urgency severity and bother questionnaire (USBQ) - a new validated questionnaire for the evaluation of urgency. *Neurourol Urodynam* 2008; 27(2 Suppl):144.
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22. Lowenstein L, FitzGerald MP, **Kenton K**, Brubaker L, Gruenwald I, Elliott C, Durazo R, Mueller E, Vardi Y. Validation of a real-time urodynamic measure of urinary urgency. *Neurourol Urodynam* 2008; 27(2 Suppl):138.
23. Lowenstein L, FitzGerald MP, **Kenton K**, G Pillar, Kenton K, Mueller E, Brubaker L. Consider a diagnosis of obstructive sleep apnea in patients with nocturia even when daytime overactive bladder syndrome is present. *Neurourol Urodynam* 2008; 27(2 Suppl):139.
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26. Davis C, **Kenton K**, Lowenstein L, Mueller E, FitzGerald MP, Brubaker L. Sensory neural changes are present in the lower urinary tract of women after reconstructive pelvic surgery. *Neurourol Urodynam* 2008; 27(2 Suppl):150.
27. **Kenton K**, Pham T, Mueller E, FitzGerald MP, Brubaker L. Patient Readiness: Important Predictor of Surgical Readiness. *J Pelvic Surgery* 2007; 13(2):60.
28. Rickey L, Graziano S, Lowenstein L, Mueller E, Summers S, **Kenton K**. Clinical Anatomy and Surgical Skills Training (CASST): Assessment of Learners. *J Pelvic Surgery* 2007; 13(2):60.
29. Fitz A, Mueller E, **Kenton K**, FitzGerald MP, Brubaker L. Putting things back where they belong: short-term anatomic outcomes of high uterosacral ligament suspension at the time of hysterectomy for prolapse. *J Pelvic Surgery* 2007;13(2):60.
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31. **Kenton K**, Pham T, Brubaker L. Nearly half of women having reconstructive pelvic surgery report new pelvic symptoms postoperatively. *J Pelvic Surgery* 2007; 13(2):60.
32. Lowenstein L, FitzGerald MP, **Kenton K**, BrubakerL, Gruenwald I, Elliott C, Durazo R, Mueller E, Vardi Y. Validation of a real-time urodynamic measure of urinary urgency. *J Pelvic Surg* 2007; 13:248-9.
33. Mahajan ST, FitzGerald M, **Kenton K**, Brubaker L. The second continence procedure: Do results depend on what was done first? *J Pelvic Surgery* 2006;12(2):111.
34. Dooley YT, West K, **Kenton K**, FitzGerald M, Brubaker L. Symptoms and anatomy are poorly correlated in women with advanced prolapse. *J Pelvic Surgery* 2006;12(2):97.
35. Sultana CJ, **Kenton K**, Ricci E. Training in pelvic floor medicine: a survey of Ob/Gyn program directors. *J Pelvic Surgery* 2006;12(2):93.



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37. **Kenton K**, Brubaker L, FitzGerald MP, Creasman J, Bradley C, Kraus S, Brown J. "No Opinion": An Opinion of Many Incontinent Women. *Int Urogynecol J* 2006;17(Suppl. 2):S152.
38. Dooley Y, **Kenton K**, Durazo-Arvizu R, Cao G, Luke A, Kramer H, Brubaker L. Black Women Report A Lower Prevalence of Stress Urinary Incontinence Than Other Racial Groups. *Int Urogynecol J* 2006;17(Suppl. 2):S153.
39. Dooley Y, West K, **Kenton K**, FitzGerald MP, Brubaker L. Bowel Symptoms and POP-Q Stage are Poorly Correlated. *Int Urogynecol J* 2006;17(Suppl. 2):S160.
40. **Kenton K**. Team Sacrocolpopexy. *Int Urogynecol J* 2006;17(Suppl. 2):S184.
41. Lowenstein L, Dooley Y, Rickey L, **Kenton K**, FitzGerald MP, Brubaker L. Are Women Who Leak At Lower Volumes More Bothered By Incontinence? *Int Urogynecol J* 2006;17(Suppl. 2):S233.
42. Lowenstein L, Dooley Y, **Kenton K**, FitzGerald MP, Tempelhof MT, Brubaker L. Do Patient Self-Reported Goals Correlate With PFDI Scores and Bother? *Int Urogynecol J* 2006;17(Suppl. 2):S267.
43. Mueller ER, **Kenton KS**, Rooney K, Shott S, Brubaker L. Isolated Cystocele Repair May Undertreat Apical Prolapse. *Int Urogynecol J* 2006; 17(Suppl. 2):S264.
44. Lowenstein L, Brubaker L, **Kenton K**, FitzGerald MP. The Nights Are The Worst: Prevalence and Impact of Nocturia. *Int Urogynecol J* 2006; 17(Suppl. 2):S264.
45. Mahajan ST, FitzGerald MP, **Kenton K**, Brubaker L. Reliability of the MESA questionnaire as a screening tool for urinary incontinence. *J Pelvic Surgery* 2005; 11(2):81.
46. Zyczynski H, Lloyd LK, **Kenton K**, Menefee S, Boreham M, Stoddard AM for the UITN. Correlation of Q-tip values and point Aa in stress incontinent women. *J Pelvic Surgery* 2005; 11(2):80.
47. Khan FG, Graziano S, **Kenton K**, Shott S, and Brubaker L. Antenatal measures of stress incontinence in predicting postpartum stress incontinence. *J Pelvic Surgery* 2004; 10(1): S64-5.
48. Khan FG, Mahajan S, **Kenton K**, FitzGerald MP, and Brubaker L. Can simple questions substitute for the MESA? *J Pelvic Surgery* 2004; 10(1): S64.
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50. Mueller E, **Kenton K**, FitzGerald MP, and Brubaker L. Striated urethral sphincter activity is not affected by pelvic organ prolapse despite changes in maximal urethral closure pressure. *Neurourol Urodyn* 2004; 23(5):422-3.
51. Elkadry E, White P, **Kenton K**, FitzGerald MP, Shott S, and Brubaker L. Pelvic floor symptoms increase after childbirth even after a low birth weight delivery. *J Pelvic Medicine* 2003; 9(5):233.
52. Simmons J, **Kenton K**, FitzGerald MP, and Brubaker L. Current Perception Threshold (CPT) measurements of the urethra and bladder in asymptomatic women. *J Pelvic Medicine* 2003; 9(5):258.

53. **Kenton K**, Hays K, and Brubaker L. What are patients learning on the internet? *Int Urogynecol J* 2001;12(1):S1.
54. **Kenton K**, Shott S, and Fenner D. The relationship of pelvic floor strength and genital hiatus size to posterior compartment dysfunction. *Int Urogynecol J* 1999;10(1): S14.

## **Presentations at Scientific Meetings**

### ***National***

1. **Kenton K** for the Pelvic Floor Disorders Network. Overall Pelvic Floor Symptoms Improve Similarly After Pessary and Behavioral Treatment of Stress Incontinence. Overall Pelvic Floor Symptoms Improve Similarly After Pessary and Behavioral Treatment of Stress Incontinence. Oral presentation, 2010 American Urogynecologic Society Annual Scientific Meeting in Long Beach, California.
2. Ramm O, Mueller E, Brubaker L, Lowenstein L, **Kenton K**. Complex Repetitive Discharges are Common in Normal Women. Oral presentation, 2010 American Urogynecologic Society Annual Scientific Meeting in Long Beach, California.
3. Abbasy S, May A, Mueller E, Brubaker L, FitzGerald M, **Kenton K**. Older Women Seeking Care for Pelvic Floor Disorders Report Similar Goals and Treatment Choices Compared to Younger Women. Short oral presentation, 2010 American Urogynecologic Society Annual Scientific Meeting in Long Beach, California.
4. Lowenstein L, Rickey L, **Kenton K**, FitzGerald M, Brubaker L, Fordham J, Mueller E. Reliability & Responsiveness of the Urgency Severity and Life Impact Questionnaire. Short Oral presentation, 2010 American Urogynecologic Society Annual Scientific Meeting in Long Beach, California.
5. Tarr M, Mueller E., Polcari A, Summers S, **Kenton K**. Development of a Robotic Surgical Training Curriculum for Gynecology & Urology Residents: Robotic Objective Structured Assessment of Technical Skills (ROSATS). Poster, 2010 AUGS Annual Scientific Meeting in Long Beach, California.
6. Anger J, Mueller E, Tarnay C, Connor S, Pantuck A, Schulam P, Kwan L, **Kenton K**.. Methodology of the Abdominal Colpopexy: Comparison of Endoscopic Surgical Strategies (ACCESS) Trial. Poster, 2010 American Urogynecologic Society Annual Scientific Meeting in Long Beach, California.
7. Lowenstein L, Rickey L, **Kenton K**, FitzGerald MP, Brubaker L, Tulke M, Fordham J, Mueller E. Test-Retest Reliability of the Urgency, Severity and Impact Questionnaire (USIQ) for Patients with Overactive Bladder. Poster, 2010 AUGS Annual Scientific Meeting in Long Beach, California.
8. **Kenton K**, Brubaker L, Mueller E. Urethral Innervation Better in Continent Women than Stress Incontinent Women. Poster, 2009 Annual Meeting of the International Continence Society, San Francisco, California.
9. Abbasy S, Michelfelder A, **Kenton K**, Mueller E, Abbasy S, FitzGerald MP. Home-based Hypnotherapy for Overactive Bladder. Poster presentation, 2009 Annual Meeting of the International Continence Society, San Francisco, California.
10. Lowenstein L, **Kenton K**, Brubaker L, Mueller E, Durazo-Arvizu R, Ladwig-Scott E, FitzGerald MP. Solifenacin Objectively Decreases Urinary Urge Sensation in Women with OAB. Poster presentation, 2009 Annual Meeting of the International Continence Society, San Francisco, California.
11. **Kenton K**, Mueller E, Lowenstein L, Brubaker L. Urethral Function of Women with Detrusor Overactivity is Intermediate that of Continent and Stress Incontinent Women. Oral presentation, 2009 Annual American Urologic Association Meeting, Hollywood, Florida.

12. Tarr M, Wolfe R, Farooq A, Mueller E, Brubaker L, **Kenton K**. Robot-assisted Laparoscopic Sacrocolpopexy versus Open Sacrocolpopexy: A Single Institution Retrospective Cohort of Perioperative and Short-Term Outcomes. Poster, 2009 Annual American Urologic Association Meeting, Hollywood, Florida.
13. Abbasy S, Lowenstein L, Durazo-Arvizu R, Fordham J, Pate P, Mueller E, **Kenton K**, Brubaker L, FitzGerald MP. Lower Urinary Tract Sensation is Altered with Aging. Poster, 2009 Annual American Urologic Association Meeting, Hollywood, Florida.
14. Abbasy S, Tarr M, Pham T, Brubaker L, **Kenton K**, Mueller E. Measurement of Transurethral Bladder Neck Distraction during Tension-Free Vaginal Tape Procedure. Oral Presentation, 2009 Annual American Urologic Association Meeting, Hollywood, Florida.
15. Abbasy S, Pham T, Shoham D, Guichan C, FitzGerald MP, **Kenton K**, Mueller E, Brubaker L. The Incidences of Urogenital Fistula and Trachelectomy have Decreased Despite the Rise of Laparoscopy Hysterectomy and Supracervical Hysterectomy Procedures. Poster, 2009 Annual American Urologic Association Meeting, Hollywood, Florida.
16. Pham T, Burgart A, **Kenton K**, Mueller E, Brubaker L. Current use of Pelvic Organ Prolapse Quantification by AUGS and ICS Members. Poster, 2009 Annual American Urologic Association Meeting, Hollywood, Florida.
17. Pham T, Polcari A, Brubaker L, FitzGerald MP, Mueller E, **Kenton K**. Surgical Outcomes of Secondary Continence Surgeries. Poster, 2009 Annual American Urologic Association Meeting, Hollywood, Florida.
18. Spirka T, **Kenton K**, Brubaker L, Damaser M. A Clinically-Relevant Model of Stress Urinary Incontinence: What is the Effect of Material Properties on the Finite Element Simulation of the Bladder, Urethra and Support Structures During a Cough. Poster, 2009 Annual American Urologic Association Meeting, Hollywood, Florida.
19. Mueller ER, **Kenton K**. Diagnosis and Robotic Repair of Ureteral Structure Following an Intra-Operative Failed Open End to End Anastomosis. Poster, 2009 Annual American Urologic Association meeting, Hollywood, Florida.
20. Brubaker L, **Kenton K**. Maintaining the Pipeline to Academia and Clinical Research: An Ob-Gyn Research Education Program. CREOG & APGO Annual Meeting 2009. San Diego, CA. March 2009.
21. Effecting change in resident education: Development of a family planning curriculum at a faith based academic institution. Guiahi M, Summers S, **Kenton K**, Westhoff C. CREOG/APGO Annual Meeting 2009. San Diego, CA. March 2009.
22. Teaching everything about contraceptive health (TEACH): Using a six-step approach to guide curriculum development. Guiahi M, Heraty S, Lukens M, Trester M, Eisenberg D, Summers S, **Kenton K**. CREOG/APGO Annual Meeting 2009. San Diego, CA. March 2009.
23. Tolterodine cause measurable restoration of urethral sensation in women with urge urinary incontinence. **Kenton K**, Lowenstein L, Brubaker L. American Urogynecologic Society 29<sup>th</sup> Annual Scientific Meeting. Chicago, IL. September 2008.
24. Urgency severity and bother questionnaire (USBQ) - a new validated questionnaire for the evaluation of urgency. Lowenstein L, Hatchett L, **Kenton K**, Brubaker L, Durazo-Arvizu R, Goldman K, Mueller ER, FitzGerald MP. Annual Meeting of the Society for Urodynamics and Female Urology. Miami, FL. February 2008.

25. Validation of a real-time urodynamic measure of urinary urgency. Lowenstein L, FitzGerald MP, **Kenton K**, Brubaker L, Gruenwald I, Elliott C, Durazo R, Mueller E, Vardi Y. Annual Meeting of the Society for Urodynamics and Female Urology. Miami, FL. February 2008.
26. Consider a diagnosis of obstructive sleep apnea in patients with nocturia even when daytime overactive bladder syndrome is present. Lowenstein L, FitzGerald MP, **Kenton K**, G Pillar, Kenton K, Mueller E, Brubaker L. Annual Meeting of the Society for Urodynamics and Female Urology, Miami, FL. February 2008.
27. Sensory neural changes are present in the lower urinary tract of women after reconstructive pelvic surgery. Davis C, **Kenton K**, Lowenstein L, Mueller E, FitzGerald MP, Brubaker L. Annual Meeting of the Society for Urodynamics and Female Urology. Miami, FL. February 2008.
28. Clinical Anatomy and Surgical Skills Training (CASST): A multidisciplinary, multicenter program. **Kenton K**, Graziano S, Mueller E, Summers S, Rickey L, Oldham L, Pombar X, Turner F, Darrell B. Society of Gynecologic Surgeons 32<sup>nd</sup> Annual Scientific Meeting. Tucson, AZ. April 2006.
29. Can advanced stages of anterior or posterior vaginal wall prolapse occur without apical involvement? Rooney K, Mueller E, **Kenton K**, FitzGerald MP, Brubaker L. Society of Gynecologic Surgeons 32<sup>nd</sup> Annual Scientific Meeting. Tucson, AZ. April 2006.
30. Training in pelvic floor medicine: a survey of Ob/Gyn program directors. Sultana CJ, **Kenton K**, Ricci E. Society of Gynecologic Surgeons 32<sup>nd</sup> Annual Scientific Meeting. Tucson, AZ. April 2006.
31. Symptoms and anatomy are poorly correlated in women with advanced prolapse. Dooley YT, West K, **Kenton K**, FitzGerald M, Brubaker L. Society of Gynecologic Surgeons 32<sup>nd</sup> Annual Scientific Meeting. Tucson, AZ. April 2006.
32. The second continence procedure: Do results depend on what was done first? Mahajan ST, FitzGerald M, **Kenton K**, Brubaker L. Society of Gynecologic Surgeons 32<sup>nd</sup> Annual Scientific Meeting. Tucson, AZ. April 2006.
33. How Are Patient's Goals Related to Quality of Life? Lowenstein L, Dooley Y, **Kenton K**, FitzGerald MP, Mueller E, Brubaker L. American Urogynecologic Society 27th Annual Scientific Meeting. Palm Springs, CA. October 2006.
34. Is Mixed Incontinence More Bothersome Than Pure Stress or Pure Urge Incontinence? Dooley Y, Rickey L, Lowenstein L, **Kenton K**, FitzGerald MP, West K, Brubaker L. American Urogynecologic Society 27th Annual Scientific Meeting. Palm Springs, CA. October 2006.
35. Nocturia As Clinical Predictor of Obstructive Sleep Apnea. Garcia J, Undevia N, **Kenton K**, Mueller E, FitzGerald MP. American Urogynecologic Society 27th Annual Scientific Meeting. Palm Springs, CA. October 2006.
36. "No Opinion": An Opinion of Many Incontinent Women. **Kenton K**, Brubaker L, FitzGerald MP, Creasman J, Bradley C, Kraus S, Brown J. American Urogynecologic Society 27th Annual Scientific Meeting. Palm Springs, CA. October 2006.
37. Localization of the urge to void differs in patients with Painful Bladder Syndrome. FitzGerald MP, **Kenton K**, Brubaker L. Society of Urodynamics and Female Urology Annual Meeting. Orlando, FL. February 2005.
38. Regional profile of adrenergic, cholinergic, and serotonergic receptor subtypes in the human female urethra. Kontak JA, Battaglia G, Walter J, and **Kenton K**. Joint Scientific Meeting of American Urogynecologic Society and Society of Gynecologic Surgeons. San Diego, CA. August 2004.

39. The POP-Q can be streamlined. Silver A, **Kenton K**, FitzGerald MP, and Brubaker L. Society for Urodynamics and Female Urology, Winter Scientific Meeting. Scottsdale, AZ. February 2004.
40. Repeat cesarean and primary elective cesarean: recently trained obstetrician-gynecologist practice patterns and options. **Kenton K**, Brincat C, Mutone M, and Brubaker L. Central Association of Obstetrician and Gynecologists Scientific Meeting. Washington D.C. October 2004.
41. Patient selected goals: a new perspective on surgical outcome. Elkadry E, **Kenton K**, FitzGerald MP, Shott S, and Brubaker L. Society of Gynecologic Surgeons 29<sup>th</sup> Annual Meeting. Anaheim, CA. March 2003.
42. Sexual activity and Pessary continuation: clinical predictors of pessary use. Brincat C, **Kenton K**, FitzGerald MP, and Brubaker L. American Urogynecologic Society 24<sup>th</sup> Annual Scientific Meeting. Hollywood, FL. September 2003.
43. Anal Incontinence in women presenting for gynecologic care: Prevalence, risk factors and impact upon quality of life. Boreham MK, Aronson MP, Gregory WT, **Kenton K**, McIntire DD, Nager CW, Richter HE, Schaffer JI, and Vogt V. Society of Gynecologic Surgeons 29<sup>th</sup> Annual Meeting. Anaheim, CA. March 2003.
44. In your dreams: a sliding bladder hernia. **Kenton K**, Mueller E, and Brubaker L. American College of Obstetricians & Gynecologists 50<sup>th</sup> Annual Clinical Meeting. "Stump the Professors". Los Angeles, CA. May 2002.
45. The effect of vaginal delivery on urethral mobility. **Kenton K**, Carney M, Davies S, Shott S, and Brubaker L. American Urogynecologic Society 23<sup>rd</sup> Annual Scientific Meeting. San Francisco, CA. October 2002.
46. The relationship between urethral pressure and striated urethral sphincter activity during filling. **Kenton K**, FitzGerald MP, Brubaker L. American Urogynecologic Society 23<sup>rd</sup> Annual Scientific Meeting. San Francisco, CA. October 2002.
47. Do mothers remember key events during labor? Elkadry E, **Kenton K**, White P, and Brubaker L. American Urogynecologic Society 23<sup>rd</sup> Annual Scientific Meeting. San Francisco, CA. October 2002.
48. Open Burch urethropexy has a low rate of perioperative complications. **Kenton K**, Oldham L, and Brubaker L. American Urogynecologic Society 22<sup>nd</sup> Annual Scientific Meeting. Chicago, IL. October 2001.
49. Survey on teaching in the operating room. **Kenton K**, Fenner D. Society of Gynecologic Surgeon's Annual Meeting. New Orleans, LA. February 2000.
50. Current perception threshold evaluation of the female lower urinary tract. **Kenton K**, Fueller E, and Benson JT. American Association of Electrodiagnostic Medicine 47<sup>th</sup> Annual Meeting. Philadelphia, PA. September 2000.
51. What are patient's learning on the internet? **Kenton K**, Hays K, Shott S, and Brubaker L. American Urogynecologic Society 21<sup>st</sup> Annual Scientific Meeting. Hilton Head, S.C. October 2000.
52. Role of urethral EMG in predicting outcome of Burch retropubic urethropexy. **Kenton K**, FitzGerald MP, and Brubaker L. American Urogynecologic Society 21<sup>st</sup> Annual Scientific Meeting. Hilton Head, S.C. October 2000.
53. Relationship between levator ani contraction and motor unit activation in the urethral sphincter. **Kenton K**, Brubaker L. American Urogynecologic Society 21<sup>st</sup> Annual Scientific Meeting. Hilton Head, S.C. October 2000.



54. Quality of life instruments are responsive to change following surgery for genuine stress incontinence. FitzGerald MP, **Kenton K**, and Brubaker L. American Urogynecologic Society 21<sup>st</sup> Annual Scientific Meeting. Hilton Head, S.C. October 2000.
55. Outcome following recto-vaginal fascia reattachment for rectocele repair. **Kenton K**, Shott S, and Brubaker L. Society of Gynecologic Surgeon's Annual Meeting. San Diego, CA. February 1999.
56. A comparison of women with primary and recurrent pelvic organ prolapse. **Kenton K**, Sadowski D, Shott S, and Brubaker L. American Urogynecologic Society 19<sup>th</sup> Annual Meeting. Washington, DC. November 1998.
57. Relationship of pelvic floor muscle strength and genital hiatus size to posterior compartment dysfunction. **Kenton K**, Shott S, and Fenner D. American Urogynecologic Society's 19<sup>th</sup> Annual Meeting. Washington, DC. November 1998.
58. Fluoroscopic rectal parameters during defecation: a study of rectocele formation. **Kenton K**, Brubaker L. American Urogynecologic Society's 17<sup>th</sup> Annual Meeting. Seattle, WA. October 1995.

### **International**

1. Risk factors for urge incontinence after continence surgery. **Kenton K**, Richter HE, Litman H, Lukacz E, Leng W, Lemack G, Chai TC, Arisco A, Tennstedt S, Steers W. International Urogynecologic Association. Lake Como, Italy. June 2009.
2. Effect of material properties. Spirka T, **Kenton K**, Brubaker L, Damaser, M. Urodynamic cough simulation: XII International Symposium on Computer Simulation in Biomechanics. Cape Town, South Africa. July 2009
3. Is mixed incontinence more bothersome than pure stress or urge incontinence? Dooley Y, Rickey L, Lowenstein L, **Kenton K**, FitzGerald MP, Brubaker L. 31<sup>st</sup> Annual International Urogynecologic Association Meeting. Athens, Greece. September 2006.
4. Black women report a lower prevalence of stress urinary incontinence than other racial groups. Dooley Y, **Kenton K**, Durazo-Arvizu R, Cao G, Luke A, Kramer H, Brubaker L. 31<sup>st</sup> Annual International Urogynecologic Association Meeting. Athens, Greece. September 2006.
5. Team Sacrocolpopexy. **Kenton K**, Dooley Y, Brubaker L. 31<sup>st</sup> Annual International Urogynecologic Association Meeting. Athens, Greece. September 2006.
6. Are Women Who Leak At Lower Volumes More Bothered By Incontinence? Lowenstein L, Dooley Y, Rickey L, **Kenton K**, FitzGerald MP, Brubaker L. 31<sup>st</sup> Annual International Urogynecologic Association Meeting. Athens, Greece. September 2006.
7. Do Patient Self-Reported Goals Correlate With PFDI Scores and Bother? Lowenstein L, Dooley Y, **Kenton K**, FitzGerald MP, Tempelhof MT, Brubaker L. 31<sup>st</sup> Annual International Urogynecologic Association Meeting. Athens, Greece. September 2006.
8. Isolated Cystocele Repair May Undertreat Apical Prolapse. Mueller ER, **Kenton KS**, Rooney K, Shott S, Brubaker L. 31<sup>st</sup> Annual International Urogynecologic Association Meeting. Athens, Greece. September 2006.
9. The Nights Are The Worst: Prevalence and Impact of Nocturia. Lowenstein L, Brubaker L, **Kenton K**, FitzGerald MP. 31<sup>st</sup> Annual International Urogynecologic Association Meeting. Athens, Greece. September 2006.

10. Evidence of altered neuromuscular function in the striated urethral sphincter of women with prior continence procedures. **Kenton K**, Mahajan S, FitzGerald MP, Brubaker L. International Urogynecologic Society Annual Meeting. Copenhagen, Denmark. August 2005.
11. What's a clinician to do? Believe the patient or her diary? **Kenton K**, FitzGerald MP, Brubaker L. International Continence Society 35<sup>th</sup> Annual Meeting. Montreal, Canada. September 2005.
12. Cystoscopic intradetrusor Botulinum A Toxin injection for the treatment of detrusor overeractivity incontinence. Mahajan S, **Kenton K**, Brubaker L. International Urogynecologic Society Annual Meeting. Copenhagen, Denmark. August 2005.
13. Patient Selected Goals: Perspectives on Surgical Outcomes One Year After Surgery. Mahajan S, Elkadry E, **Kenton K**, FitzGerald M, Shott S, and Brubaker L. International Continence Society Annual Meeting. Paris, France. August 2004.
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# Exhibit B

# **Kimberly Kenton**

**Reliance List**  
***in Addition to Materials Referenced in Report***

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